

11-09-00  
A  
ARTHROCARE CORPORATION  
595 N. Pastoria Avenue  
Sunnyvale, CA 94086  
(408) 736-0224  
Customer No. 021394

Atty. Docket No. A-14

"Express Mail" Label No. EK913748984US

Date of Deposit November 8, 2000

BOX PATENT APPLICATION  
ASSISTANT COMMISSIONER FOR PATENTS  
Washington, D. C. 20231

I hereby certify that this is being deposited with the  
United States Postal Service "Express Mail Post Office  
to Addressee" service under 37 CFR 1.10 on the date  
indicated above and is addressed to:  
Assistant Commissioner for Patents  
Washington, D.C. 20231

By: *John T. Raffle*

11/08/00  
Transmitted herewith for filing is the ☐ patent application,  
☐ design patent application, ☒ continuation-in-part patent  
application of

Inventor(s): **JEAN WOLOSZKO, TERRY S. DAVISON, DAVID C. HOVDA, HIRA V. THAPLIYAL and  
PHILIP E. EGGERS**

For: **SYSTEMS AND METHODS FOR TISSUE ABLATION AND RESECTION**

☒ This application claims priority from each of the following Application Nos./filing dates:  
60/210,567 / June 9, 2000; 09/197,013 / November 20, 1998; 09/010,382 / January 21, 1998;  
08/990,374 / December 15, 1997; 08/485,219 / June 7, 1995

☐ Please amend this application by adding the following before the first sentence: --This application claims the benefit of U.S.  
Provisional Application No. \_\_\_\_\_, filed \_\_\_\_\_, the disclosure of which is incorporated by reference.--

Enclosed are:

- ☒ 50 sheet(s) of ☐ formal ☒ informal drawing(s).  
☒ An assignment of the invention to ArthroCare Corporation  
☒ A ☒ signed ☐ unsigned Declaration & Power of Attorney.  
☐ A ☐ signed ☐ unsigned Declaration.  
☐ A Power of Attorney by Assignee.  
☒ A verified statement to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27 ☒ is enclosed ☐ was filed  
in the earliest of the above-identified patent application(s).  
☐ Information Disclosure Statement under 37 CFR 1.97.  
☐ A petition to extend time to respond in the parent application of this continuation-in-part application.  
☒ The filing fee has been calculated as shown below:

	(Col. 1)	(Col. 2)
FOR:	NO. FILED	NO. EXTRA
BASIC FEE		
TOTAL CLAIMS	85 -20=	* 65
INDEP CLAIMS	5 -3=	* 2
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENTED		

SMALL ENTITY

RATE	FEE
	\$355
X9=	\$585
x40=	\$80
+130=	\$
TOTAL	\$1020

OR  
OR  
OR  
OR  
OR  
OR

OTHER THAN A  
SMALL ENTITY

RATE	FEE
	\$790
X18=	\$
x80=	\$
+260=	\$
TOTAL	\$

\* If the difference in Col. 1 is less than zero, enter "0" in Col. 2

Please charge Deposit Account No. 50-0359 as follows:

- ☒ Filing fee  
☒ Any additional fees associated with this paper or  
during the pendency of this application  
☐ The issue fee set in 37 CFR 1.18 at or before mailing of the Notice  
of Allowance, pursuant to 37 CFR 1.311(b).

\$ 1,020.00

☐ A check for \$ \_\_\_\_\_ is enclosed.  
1 extra copy of this sheet is enclosed.

Respectfully submitted,  
ARTHROCARE CORPORATION

ph: (408) 736-0224

*John T. Raffle*  
John T. Raffle, Reg. No.: 38,555

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS**  
**(37 CFR 1.9(f) & 1.27(c)) - SMALL BUSINESS CONCERN**

Applicant or Patentee: Jean Woloszko et al.Application or Patent No.: unassignedFiled or Issued: herewithTitle: SYSTEMS AND METHODS FOR TISSUE ABLATION AND RESECTION

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:  
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

Name of Small Business Concern: ArthroCare CorporationAddress of Small Business Concern: 595 N. Pastoria Avenue, Sunnyvale, California 94085-2936

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled SYSTEMS AND METHODS FOR TISSUE ABLATION AND RESECTION by inventor(s) Jean Woloszko, David C. Hovda, Hira V. Thapliyal, Philip E. Eggers and Terry S. Davison described in:

- ☒ the specification filed herewith.  
☐ Application No. \_\_\_\_\_, filed \_\_\_\_\_.  
☐ Patent No. \_\_\_\_\_, issued \_\_\_\_\_.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

\*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

Name \_\_\_\_\_

Address \_\_\_\_\_

☐ Individual☐ Small Business Concern☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Michael A. BakerTitle of Person if Other than Owner: Chief Executive OfficerAddress of Person Signing: 595 N. Pastoria Ave., Sunnyvale, CA 94085-2936

Signature \_\_\_\_\_

Date \_\_\_\_\_

**PATENT APPLICATION**

**SYSTEMS AND METHODS FOR TISSUE  
ABLATION AND RESECTION**

**Inventors:**

JEAN WOLOSZKO, a citizen of France,  
residing at 1694 Columbia Drive  
Mountain View, California 94040;

TERRY S. DAVISON, a citizen of Canada, residing at  
10398 #B, Meadow Place  
Cupertino, California 95014;

DAVID C. HOVDA, a citizen of the United States  
of America, residing at 1900 Miramonte Avenue  
Mountain View, California 94040;

HIRA V. THAPLIYAL, a citizen of the United States  
of America, residing at 1192 Volti Lane  
Los Altos, California 94024; and

PHILIP E. EGGERS, a citizen of the United States  
of America, residing at 5366 Reserve Drive  
Dublin, Ohio 43017;

**Assignee:**

ArthroCare Corporation  
595 North Pastoria Avenue  
Sunnyvale, California 94085-2936

009071 " 5E060260

**SYSTEMS AND METHODS FOR TISSUE  
ABLATION AND RESECTION**

5

**RELATED APPLICATIONS**

The present invention is a claims priority from Provisional Patent Application No. 60/210,567, filed June 9, 2000 (Attorney Docket No. A-14P), which is a continuation-in-part of U.S. Patent Application No. 09/197,013, filed November 20, 1998 (Attorney Docket No. A-6-1) which is a continuation-in-part of U.S. Patent Application No. 09/010,382, filed January 21, 1998 (Attorney Docket No. A-6), which is a continuation-in-part of U.S. Patent Application No. 08/990,374, filed on December 15, 1997 (Attorney Docket No. E-3), which is a continuation-in-part of U.S. Patent Application No. 08/485,219, filed on June 7, 1995 (Attorney Docket No. 16238-000600), now U.S. Patent No. 5,697,281, which is a continuation-in-part of PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, now U.S. Patent No. 5,697,909 (Attorney Docket 16238-000440), which was a continuation-in-part of U.S. Patent Application No. 08/059,681, filed on May 10, 1993 (Attorney Docket 16238-000420), the complete disclosures of which are incorporated herein by reference for all purposes. The present invention also derives priority from Provisional Patent Application 60/062,996 filed on October 23, 1997 (Attorney Docket No. 16238-007300).

The present invention is related to commonly assigned co-pending Provisional Patent Application 60/062,997 filed on October 23, 1997 (Attorney Docket No. 16238-007400), non-provisional U.S. Patent Application No. 08/977,845, filed November 25, 1997 (Attorney Docket No. D-2), which is a continuation-in-part of Application No. 08/562,332, filed November 22, 1995 (Attorney Docket No. 016238-000710), the complete disclosures of which are incorporated herein by reference for all purposes. The present invention is also related to U.S. Patent Application Nos. 09/109,219, 09/058,571, 08/874,173 and 09/002,315, filed on June 30, 1998, April 10, 1998, June 13, 1997, and January 2, 1998, respectively (Attorney Docket Nos. CB-1, CB-2, 16238-005600 and C-9, respectively) and U.S. Patent Application No. 09/054,323, filed on April 2, 1998 (Attorney Docket No. E-5), U.S. Patent Application No. 09/010,382,



09709035 110800

filed January 21, 1998 (Attorney Docket A-6), and U.S. Patent Application No. 09/032,375, filed February 27, 1998 (Attorney Docket No. CB-3), U.S. Patent Application Nos. 08/977,845, filed on November 25, 1997 (Attorney Docket No. D-2), 08/942,580, filed on October 2, 1997 (Attorney Docket No. 16238-001300), U.S. Application No. 08/753,227, filed on November 22, 1996 (Docket 16238-002200), U.S. Application No. 08/687792, filed on July 18, 1996 (Docket No. 16238-001600), the complete disclosures of which are incorporated herein by reference for all purposes. The present invention is also related to commonly assigned U.S. Patent No. 5,683,366, filed November 22, 1995 (Attorney Docket 16238-000700), the complete disclosure of which is incorporated herein by reference for all purposes.

### BACKGROUND OF THE INVENTION

The present invention relates generally to the field of electrosurgery, and more particularly to surgical devices and methods which employ high frequency electrical energy to resect, coagulate, ablate, and aspirate cartilage, bone and other tissue, such as sinus tissue, adipose tissue, or meniscus, cartilage, and synovial tissue in a joint. The present invention also relates to apparatus and methods for removing tissue at a target site by a combination of ablation and mechanical resection.

Conventional electrosurgical methods generally reduce patient bleeding associated with tissue cutting operations and improve the surgeon's visibility. These electrosurgical devices and procedures, however, suffer from a number of disadvantages. For example, monopolar electrosurgery methods generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient's skin. In addition, since the defined path through the patient's body has a relatively high electrical impedance, large voltage differences must typically be applied between the active and return electrodes to generate a current suitable for cutting or coagulation of the target tissue. This current, however, may inadvertently flow along localized pathways in the body having less impedance than the defined electrical path. This situation will substantially increase the current flowing through these paths, possibly causing damage to or destroying tissue along and surrounding this pathway.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient beyond the immediate site of application of the bipolar electrodes. In bipolar devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may cause tissue desiccation or destruction at its contact point with the patient's tissue.

Another limitation of conventional bipolar and monopolar electrosurgery devices is that they are not suitable for the precise removal (i.e., ablation) of tissue. For example, conventional electrosurgical cutting devices typically operate by creating a voltage difference between the active electrode and the target tissue, causing an electrical arc to form across the physical gap between the electrode and tissue. At the point of contact of the electric arcs with tissue, rapid tissue heating occurs due to high current density between the electrode and tissue. This high current density causes cellular fluids to rapidly vaporize into steam, thereby producing a "cutting effect" along the pathway of localized tissue heating. The tissue is parted along the pathway of vaporized cellular fluid, inducing undesirable collateral tissue damage in regions surrounding the target tissue site.

In addition, conventional electrosurgical methods are generally ineffective for ablating certain types of tissue, and in certain types of environments within the body. For example, loose or elastic connective tissue, such as the synovial tissue in joints, is extremely difficult (if not impossible) to remove with conventional electrosurgical instruments because the flexible tissue tends to move away from the instrument when it is brought against this tissue. Since conventional techniques rely mainly on conducting current through the tissue, they are not effective when the instrument cannot be brought adjacent to or in contact with the elastic tissue for a long enough period of time to energize the electrode and conduct current through the tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline, both to maintain an isotonic environment and to keep the field of view clear. However, the presence of saline, which is a highly conductive electrolyte, can cause shorting of the active electrode(s) in conventional monopolar and bipolar electrosurgery. Such shorting

causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Conventional electrosurgical cutting or resecting devices also tend to leave the operating field cluttered with tissue fragments that have been removed or resected from the target tissue. These tissue fragments make visualization of the surgical site extremely difficult. Removing these tissue fragments can also be problematic. Similar to synovial tissue, it is difficult to maintain contact with tissue fragments long enough to ablate the tissue fragments *in situ* with conventional devices. To solve this problem, the surgical site is periodically or continuously aspirated during the procedure. However, the tissue fragments often clog the aspiration lumen of the suction instrument, forcing the surgeon to remove the instrument to clear the aspiration lumen or to introduce another suction instrument, which increases the length and complexity of the procedure.

Thus, there is a need for an electrosurgical apparatus which enables the aggressive removal of tissues in a controlled manner, wherein resected tissue fragments are broken down and efficiently removed from the surgical field. The instant invention provides such an apparatus, wherein tissue may be removed by a combination of mechanical resection and electrical ablation, and the quantity and quality of the tissue to be removed can be accurately controlled.

## SUMMARY OF THE INVENTION

The present invention provides systems, apparatus, kits, and methods for selectively applying electrical energy to structures within or on the surface of a patient's body. In particular, methods and apparatus are provided for resecting, cutting, partially ablating, aspirating or otherwise removing tissue from a target site, and ablating the tissue *in situ*.

In one aspect, the present invention provides an electrosurgical instrument for treating tissue at a target site. The instrument comprises a shaft having a proximal portion and a distal end portion. One or more active loop electrodes are disposed at the distal end of the shaft. The loop electrodes preferably have one or more edges that promote high electric fields. A connector is disposed near the proximal end of the shaft for electrically coupling the active loop electrodes to a high frequency source.

The active loop electrodes typically have an exposed semicircular shape that facilitates the removing or ablating of tissue at the target site. During the procedure, bodily fluid, non-ablated tissue fragments and/or air bubbles are aspirated from the target site to improve visualization.

5           At least one return electrode is preferably spaced from the active electrode(s) a sufficient distance to prevent arcing therebetween at the voltages suitable for tissue removal and or heating, and to prevent contact of the return electrode(s) with the tissue. The current flow path between the active and return electrodes may be generated by immersing the target site within electrically conductive fluid (as is typical in  
10   arthroscopic procedures), or by directing an electrically conductive fluid along a fluid path past the return electrode and to the target site (e.g., in open procedures). Alternatively, the electrodes may be positioned within a viscous electrically conductive fluid, such as a gel, at the target site, and submersing the active and return electrode(s) within the conductive gel. The electrically conductive fluid will be selected to have sufficient  
15   electrical conductivity to allow current to pass therethrough from the active to the return electrode(s), and such that the fluid ionizes into a plasma when subject to sufficient electrical energy, as discussed below. In the exemplary embodiment, the conductive fluid is isotonic saline, although other fluids may be selected, as described in co-pending Provisional Patent Application No. 60/098,122, filed August 27, 1998 (Attorney Docket  
20   No. CB-7P), the complete disclosure of which is incorporated herein by reference.

          In a specific embodiment, tissue ablation results from molecular dissociation or disintegration processes. Conventional electrosurgery ablates or cuts through tissue by rapidly heating the tissue until cellular fluids explode, producing a cutting effect along the pathway of localized heating. The present invention volumetrically  
25   removes tissue, e.g., cartilage tissue, in a cool ablation process known as Coblation®, wherein thermal damage to surrounding tissue is minimized. During this process, a high frequency voltage applied to the active electrode(s) is sufficient to vaporize an electrically conductive fluid (e.g., gel or saline) between the electrode(s) and the tissue. Within the vaporized fluid, an ionized plasma is formed and charged particles (e.g., electrons) are  
30   accelerated within the plasma to cause the molecular breakdown or disintegration of tissue components in contact with the plasma. This molecular dissociation is accompanied by the volumetric removal of the tissue. The short range of the accelerated charged particles within the plasma layer confines the molecular dissociation process to the surface layer,

thereby minimizing damage and necrosis to the underlying tissue. This process can be precisely controlled to effect the volumetric removal of tissue as thin as 10 to 50 microns with minimal heating of, or damage to, surrounding or underlying tissue structures. A more complete description of this Coblation<sup>®</sup> phenomenon is described in commonly  
5 assigned U.S. Patent No. 5,683,366, the complete disclosure of which is incorporated herein by reference.

The present invention offers a number of advantages over conventional electrosurgery, microdebrider, shaver and laser techniques for removing soft tissue in arthroscopic, sinus or other surgical procedures. The ability to precisely control the  
10 volumetric removal of tissue results in a field of tissue ablation or removal that is very defined, consistent and predictable. The shallow depth of tissue heating also helps to minimize or completely eliminate damage to healthy tissue structures, e.g., cartilage, bone and/or cranial nerves that are often adjacent the target sinus tissue. In addition, small blood vessels at the target site are simultaneously cauterized and sealed as the tissue is  
15 removed to continuously maintain hemostasis during the procedure. This increases the surgeon's field of view, and shortens the length of the procedure. Moreover, since the present invention allows for the use of electrically conductive fluid (contrary to prior art bipolar and monopolar electrosurgery techniques), isotonic saline may be used during the procedure. Saline is the preferred medium for irrigation because it has the same  
20 concentration as the body's fluids and, therefore, is not absorbed into the body as much as certain other fluids.

Systems according to the present invention generally include an electrosurgical instrument having a shaft with proximal and distal end portions, one or more active loop electrode(s) at the distal end of the shaft and one or more return  
25 electrode(s). The system can further include a high frequency power supply for applying a high frequency voltage difference between the active electrode(s) and the return electrode(s). The instrument typically includes an aspiration lumen within the shaft having an opening positioned proximal of the active electrode(s) so as to draw bodily fluids and air bubbles into the aspiration lumen under vacuum pressure.

30 In another aspect, the present invention provides an electrosurgical probe having a fluid delivery element for delivering electrically conductive fluid to the active electrode(s) and the target site. The fluid delivery element may be located on the instrument, e.g., a fluid lumen or tube, or it may be part of a separate instrument. In an

exemplary configuration the fluid delivery element includes at least one opening that is positioned around the active electrodes. Such a configuration provides an improved flow of electrically conductive fluid and promotes more aggressive generation of the plasma at the target site.

5 Alternatively, an electrically conductive fluid, such as a gel or liquid spray, e.g., saline, may be applied to the tissue. In arthroscopic procedures, the target site will typically already be immersed in a conductive irrigant, i.e., saline. In these embodiments, the apparatus may lack a fluid delivery element. In both embodiments, the electrically conductive fluid will preferably generate a current flow path between the active  
10 electrode(s) and the return electrode(s). In an exemplary embodiment, a return electrode is located on the instrument and spaced a sufficient distance from the active electrode(s) to substantially avoid or minimize current shorting therebetween and to shield the tissue from the return electrode at the target site.

In another aspect, the present invention provides a method for applying  
15 electrical energy to a target site within or on a patient's body. The method comprises positioning one or more active electrodes into at least close proximity with the target site. An electrically conductive fluid is provided to the target site and a high frequency voltage is applied between the active electrodes and a return electrode to generate relatively high, localized electric field intensities between the active electrode(s) and the target site,  
20 wherein an electrical current flows from the active electrode(s) through tissue at the target site. The active electrodes are moved in relation to the targeted tissue to resect or ablate the tissue at the target site.

In another aspect, the present invention provides a method for resecting tissue from a target site. The method comprises positioning one or more active electrodes  
25 adjacent tissue at a target site within or on a patient's body. A conductive fluid is delivered through openings that are positioned around the active electrode. High frequency voltage is applied between one or more active electrode(s) and through the conductive fluid to apply energy to the tissue at the target site. Preferably, the high frequency voltage is sufficient to remove or ablate at least a portion of the tissue.

30 In another aspect, the present invention provides an electrosurgical probe and an electrosurgical kit including the probe. The probe includes a first set of active electrodes, which may be referred to hereafter as "resection electrodes," wherein the resection electrodes are disposed on an insulating support at the shaft distal end of the

probe. The resection electrodes are adapted for both mechanical resection and electrical ablation of tissue in a controlled manner. The probe further includes a second set of active electrodes, which may be referred to hereafter as "digestion electrodes," wherein the digestion electrodes are preferably disposed in relation to an aspiration stream, the stream emanating from a target site of tissue removal, such that resected tissue fragments from the site contact one or more of the digestion electrode. The digestion electrodes are adapted for aggressively ablating tissue fragments.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

Fig. 1 is a perspective view of an electrosurgical system incorporating a power supply and an electrosurgical probe for tissue ablation, resection, incision, contraction and for vessel hemostasis according to the present invention;

Fig. 2 is a side view of an electrosurgical probe according to the present invention incorporating a loop electrode for resection and ablation of tissue;

Fig. 3 is a cross-sectional view of the electrosurgical probe of Fig. 2;

Fig. 4 is an exploded sectional view of a distal portion of the electrosurgical probe;

Figs. 5A and 5B are end and cross-sectional views, respectively, of the proximal portion of the probe;

Fig. 6 illustrates a surgical kit for removing and ablating tissue according to the present invention;

Fig. 7 is a perspective view of another electrosurgical system incorporating a power supply, an electrosurgical probe and a supply of electrically conductive fluid for delivering the fluid to the target site;

Fig. 8 is a side view of another electrosurgical probe according to the present invention incorporating aspiration electrodes for ablating aspirated tissue fragments and/or tissue strands, such as synovial tissue;

Fig. 9 is an end view of the probe of Fig. 8;

Fig. 10 is an exploded view of a proximal portion of the electrosurgical probe;

Figs. 11-13 illustrate alternative probes according to the present invention, incorporating aspiration electrodes;

Fig. 14 illustrates an endoscopic sinus surgery procedure, wherein an endoscope is delivered through a nasal passage to view a surgical site within the nasal cavity of the patient;

Fig. 15 illustrates an endoscopic sinus surgery procedure with one of the probes described above according to the present invention;

Figs. 16A and 16B illustrate a detailed view of the sinus surgery procedure, illustrating ablation of tissue according to the present invention;

Fig. 17 illustrates a procedure for treating obstructive sleep disorders, such as sleep apnea, according to the present invention;

Fig. 18 is a perspective view of another embodiment of the present invention;

Fig. 19 is a side-cross-sectional view of the electrosurgical probe of Fig. 18;

Fig. 20 is an enlarged detailed cross-sectional view of the distal end portion of the probe of Fig. 18;

Figs. 21 and 22 show the proximal end and the distal end, respectively, of the probe of Fig. 18;

Fig. 23 illustrates a method for removing fatty tissue from the abdomen, groin or thigh region of a patient according to the present invention;

Fig. 24 illustrates a method for removing fatty tissue in the head and neck region of a patient according to the present invention.

Fig. 25 is a perspective view of yet another embodiment of the present invention;

Fig. 26 is a side cross-sectional view of the electrosurgical probe of Fig. 25;

Fig. 27 is an enlarged detailed view of the distal end portion of the probe of Fig. 25;

Fig. 28 is a perspective view of the distal portion of the probe of Fig. 25;

Fig. 29 is a perspective view of an insulating member of the probe of Fig. 25;

Fig. 30 illustrates the proximal end of the probe of Fig. 25; and

Fig. 31 is an alternative embodiment of the active electrode for the probe of Fig. 25;



Fig. 32 shows an electrosurgical probe including a resection unit, according to another embodiment of the invention;

Fig. 33 shows a resection unit of an electrosurgical probe, the resection unit including a resection electrode on a resection electrode support;

5 Figs. 34A-D each show an electrosurgical probe including a resection unit, according to various embodiments of the invention;

Fig. 35A shows an electrosurgical probe including a resection unit and an aspiration device, according to the invention;

10 Fig. 35B shows an electrosurgical probe including a resection unit and a fluid delivery device, according to one embodiment of the invention;

Figs. 36A-F each show a resection unit having at least one resection electrode head arranged on a resection electrode support, according to various embodiments of the invention;

15 Fig. 37 illustrates an arrangement of a resection electrode head with respect to the longitudinal axis of a resection unit;

Fig. 38A shows, in plan view, a resection electrode support disposed on a shaft distal end of an electrosurgical probe;

Figs. 38B-D each show a profile of a resection electrode head on a resection electrode support;

20 Figs. 39A-I each show a cross-section of a resection electrode head, according to one embodiment of the invention, as seen along the lines 39A-I of Fig. 38B;

Fig. 40 shows a cross-section of a resection electrode head having an exposed cutting edge and a covered portion having an insulating layer, according to another embodiment of the invention;

25 Fig. 41A illustrates a distal end of an electrosurgical probe including a plurality of resection electrode heads, according to another embodiment of the invention;

Fig. 41B illustrates the distal end of the electrosurgical probe of Fig. 41A taken along the lines 41B-41B;

30 Fig. 41C illustrates the distal end of the electrosurgical probe of Fig. 41A taken along the lines 41C-41C;

Fig. 42A is a sectional view of a distal end portion of an electrosurgical shaft, according to one embodiment of the invention;

Fig. 42B illustrates the distal end of the shaft of Fig. 42A taken along the lines 42B-42B;

Figs. 43A-D are side views of the shaft distal end portion of an electrosurgical probe, according to another embodiment of the invention;

5 Figs. 44A-D each show a resection unit in relation to a fluid delivery device, according to various embodiments of the invention;

Fig. 45 shows a shaft distal end portion of an electrosurgical probe, according to one embodiment of the invention;

10 Fig. 46 schematically represents a surgical kit for resection and ablation of tissue, according to another embodiment of the invention;

Figs. 47A-B schematically represent a method of performing a resection and ablation electrosurgical procedure, according to another embodiment of the invention; and

Fig. 48 schematically represents a method of making a resection and ablation electrosurgical probe, according to yet another embodiment of the invention.

## 15 DESCRIPTION OF SPECIFIC EMBODIMENTS

The present invention provides systems and methods for selectively applying electrical energy to a target location within or on a patient's body. The present invention is particularly useful in procedures where the tissue site is flooded or submerged with an electrically conductive fluid, such as arthroscopic surgery of the knee, shoulder, ankle, 20 hip, elbow, hand or foot. In addition, tissues which may be treated by the system and method of the present invention include, but are not limited to, prostate tissue and leiomyomas (fibroids) located within the uterus, gingival tissues and mucosal tissues located in the mouth, tumors, scar tissue, myocardial tissue, collagenous tissue within the eye or epidermal and dermal tissues on the surface of the skin. Other procedures for which 25 the present invention may be used include laminectomy/diskectomy procedures for treating herniated disks, decompressive laminectomy for stenosis in the lumbosacral and cervical spine, posterior lumbosacral and cervical spine fusions, treatment of scoliosis associated with vertebral disease, foraminotomies to remove the roof of the intervertebral foramina to relieve nerve root compression, as well as anterior cervical and lumbar discectomies. The 30 present invention is also useful for resecting tissue within accessible sites of the body that are suitable for electrode loop resection, such as the resection of prostate tissue, leiomyomas (fibroids) located within the uterus, and other diseased tissue within the body.

The present invention is also useful for procedures in the head and neck, such as the ear, mouth, pharynx, larynx, esophagus, nasal cavity and sinuses. These procedures may be performed through the mouth or nose using speculae or gags, or using endoscopic techniques, such as functional endoscopic sinus surgery (FESS). These  
5 procedures may include the removal of swollen tissue, chronically-diseased inflamed and hypertrophic mucus linings, polyps and/or neoplasms from the various anatomical sinuses of the skull, the turbinates and nasal passages, in the tonsil, adenoid, epi-glottic and supra-glottic regions, and salivary glands, submucous resection of the nasal septum, excision of diseased tissue and the like. In other procedures, the present invention may be useful for  
10 collagen shrinkage, ablation and/or hemostasis in procedures for treating snoring and obstructive sleep apnea (e.g., soft palate, such as the uvula, or tongue/pharynx stiffening, and midline glossectomies), for gross tissue removal, such as tonsillectomies, adenoidectomies, tracheal stenosis and vocal cord polyps and lesions, or for the resection or ablation of facial tumors or tumors within the mouth and pharynx, such as  
15 glossectomies, laryngectomies, acoustic neuroma procedures and nasal ablation procedures. In addition, the present invention is useful for procedures within the ear, such as stapedotomies, tympanostomies or the like.

The present invention may also be useful for cosmetic and plastic surgery procedures in the head and neck. For example, the present invention is particularly useful  
20 for ablation and sculpting of cartilage tissue, such as the cartilage within the nose that is sculpted during rhinoplasty procedures. The present invention may also be employed for skin tissue removal and/or collagen shrinkage in the epidermis or dermis tissue in the head and neck, e.g., the removal of pigmentations, vascular lesions (e.g., leg veins), scars, tattoos, etc., and for other surgical procedures on the skin, such as tissue rejuvenation,  
25 cosmetic eye procedures (blepharoplasties), wrinkle removal, tightening muscles for facelifts or browlifts, hair removal and/or transplant procedures, etc.

For convenience, certain embodiments of the invention will be described primarily with respect to the resection and/or ablation of the meniscus and the synovial tissue within a joint during an arthroscopic procedure and to the ablation, resection and/or  
30 aspiration of sinus tissue during an endoscopic sinus surgery procedure, but it will be appreciated that the systems and methods can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open procedures, intravascular procedures, urology, laparoscopy, arthroscopy, thoracoscopy or

other cardiac procedures, dermatology, orthopedics, gynecology, otorhinolaryngology, spinal and neurologic procedures, oncology, and the like.

In the present invention, high frequency (RF) electrical energy is applied to one or more active electrodes in the presence of electrically conductive fluid to remove and/or modify the structure of tissue structures. Depending on the specific procedure, the present invention may be used to: (1) volumetrically remove tissue, bone or cartilage (i.e., ablate or effect molecular dissociation of the tissue structure); (2) cut or resect tissue; (3) shrink or contract collagen connective tissue; and/or (4) coagulate severed blood vessels.

In one aspect of the invention, systems and methods are provided for the volumetric removal or ablation of tissue structures. In these procedures, a high frequency voltage difference is applied between one or more active electrode(s) and one or more return electrode(s) to develop high electric field intensities in the vicinity of the target tissue site. The high electric field intensities lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). Applicant believes that the tissue structure is volumetrically removed through molecular disintegration of larger organic molecules into smaller molecules and/or atoms, such as hydrogen, oxides of carbon, hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to dehydrating the tissue material by the removal of liquid from within the cells of the tissue, as is typically the case with electrosurgical desiccation and vaporization.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize an electrically conductive fluid over at least a portion of the active electrode(s) in the region between the distal tip of the active electrode(s) and the target tissue. The electrically conductive fluid may be a gas or liquid, such as isotonic saline, delivered to the target site, or a viscous fluid, such as a gel, that is located at the target site. In the latter embodiment, the active electrode(s) are submersed in the electrically conductive gel during the surgical procedure. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltage differential between the active electrode tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conductive fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from the vapor layer to the surface of the target tissue. This energy may be in the form of energetic photons (e.g., ultraviolet

radiation), energetic particles (e.g., electrons) or a combination thereof. A more detailed description of this cold ablation phenomena, termed Coblation®, can be found in commonly assigned U.S. Patent No. 5,683,366 the complete disclosure of which is incorporated herein by reference.

5           The present invention applies high frequency (RF) electrical energy in an electrically conductive fluid environment to remove (i.e., resect, cut, or ablate) or contract a tissue structure, and to seal transected vessels within the region of the target tissue. The present invention is particularly useful for sealing larger arterial vessels, e.g., on the order of 1 mm in diameter or greater. In some embodiments, a high frequency power supply is  
10       provided having an ablation mode, wherein a first voltage is applied to an active electrode sufficient to effect molecular dissociation or disintegration of the tissue, and a coagulation mode, wherein a second, lower voltage is applied to an active electrode (either the same or a different electrode) sufficient to achieve hemostasis of severed vessels within the tissue. In other embodiments, an electrosurgical probe is provided having one or more  
15       coagulation electrode(s) configured for sealing a severed vessel, such as an arterial vessel, and one or more active electrodes configured for either contracting the collagen fibers within the tissue or removing (ablating) the tissue, e.g., by applying sufficient energy to the tissue to effect molecular dissociation. In the latter embodiments, the coagulation electrode(s) may be configured such that a single voltage can be applied to coagulate tissue  
20       with the coagulation electrode(s), and to ablate or contract the tissue with the active electrode(s). In other embodiments, the power supply is combined with the probe such that the coagulation electrode receives power when the power supply is in the coagulation mode (low voltage), and the active electrode(s) receive power when the power supply is in the ablation mode (higher voltage).

25           In the method of the present invention, one or more active electrodes are brought into close proximity to tissue at a target site, and the power supply is activated in the ablation mode such that sufficient voltage is applied between the active electrodes and the return electrode to volumetrically remove the tissue through molecular dissociation, as described below. During this process, vessels within the tissue will be severed. Smaller  
30       vessels will be automatically sealed with the system and method of the present invention. Larger vessels, and those with a higher flow rate, such as arterial vessels, may not be automatically sealed in the ablation mode. In these cases, the severed vessels may be sealed by activating a control (e.g., a foot pedal) to reduce the voltage of the power supply

and to convert the system into the coagulation mode. In this mode, the active electrodes may be pressed against the severed vessel to provide sealing and/or coagulation of the vessel. Alternatively, a coagulation electrode located on the same or a different probe may be pressed against the severed vessel. Once the vessel is adequately sealed, the surgeon  
5 activates a control (e.g., another foot pedal) to increase the voltage of the power supply and convert the system back into the ablation mode.

The present invention is particularly useful for removing or ablating tissue around nerves, such as spinal or cranial nerves, e.g., the olfactory nerve on either side of the nasal cavity, the optic nerve within the optic and cranial canals, and the palatine nerve  
10 within the nasal cavity, soft palate, uvula and tonsil, etc. One of the significant drawbacks with prior art microdebriders and lasers is that these devices do not differentiate between the target tissue and the surrounding nerves or bone. Therefore, the surgeon must be extremely careful during these procedures to avoid damage to the bone or nerves within and around the nasal cavity. In the present invention, the Coblation® process for removing  
15 tissue results in extremely small depths of collateral tissue damage as discussed above. This allows the surgeon to remove tissue close to a nerve without causing collateral damage to the nerve fibers.

In addition to the generally precise nature of the novel mechanisms of the present invention, applicant has discovered an additional method of ensuring that adjacent  
20 nerves are not damaged during tissue removal. According to the present invention, systems and methods are provided for distinguishing between the fatty tissue immediately surrounding nerve fibers and the normal tissue that is to be removed during the procedure. Nerves usually comprise a connective tissue sheath, or endoneurium, enclosing the bundles of nerve fibers to protect these nerve fibers. This protective tissue sheath typically  
25 comprises a fatty tissue (e.g., adipose tissue) having substantially different electrical properties than the normal target tissue, such as the turbinates, polyps, mucus tissue or the like, that are, for example, removed from the nose during sinus procedures. The system of the present invention measures the electrical properties of the tissue at the tip of the probe with one or more active electrode(s). These electrical properties may include  
30 electrical conductivity at one, several or a range of frequencies (e.g., in the range from 1 kHz to 100 MHz), dielectric constant, capacitance or combinations of these. In this embodiment, an audible signal may be produced when the sensing electrode(s) at the tip of the probe detects the fatty tissue surrounding a nerve, or direct feedback control can be

provided to only supply power to the active electrode(s), either individually or to the complete array of electrodes, if and when the tissue encountered at the tip or working end of the probe is normal tissue based on the measured electrical properties.

In one embodiment, the current limiting elements (discussed in detail below) are configured such that the active electrodes will shut down or turn off when the electrical impedance of tissue at the tip of the probe reaches a threshold level. When this threshold level is set to the impedance of the fatty tissue surrounding nerves, the active electrodes will shut off whenever they come in contact with, or in close proximity to, nerves. Meanwhile, the other active electrodes, which are in contact with or in close proximity to nasal tissue, will continue to conduct electric current to the return electrode. This selective ablation or removal of lower impedance tissue in combination with the Coblation® mechanism of the present invention allows the surgeon to precisely remove tissue around nerves or bone.

In addition to the above, applicant has discovered that the Coblation® mechanism of the present invention can be manipulated to ablate or remove certain tissue structures, while having little effect on other tissue structures. As discussed above, the present invention uses a technique of vaporizing electrically conductive fluid to form a plasma layer or pocket around the active electrode(s), and then inducing the discharge of energy from this plasma or vapor layer to break the molecular bonds of the tissue structure. Based on initial experiments, applicants believe that the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conductive liquid) becomes sufficiently low (i.e., less than approximately  $10^{20}$  atoms/cm<sup>3</sup> for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine to form gaseous or liquid Coblation® by-products.

The energy evolved by the energetic electrons may be varied by adjusting a variety of factors, such as: the number of active electrodes; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other

factors. Accordingly, these factors can be manipulated to control the energy level of the excited electrons. Since different tissue structures have different molecular bonds, the present invention can be configured to break the molecular bonds of certain tissue, while having too low an energy to break the molecular bonds of other tissue. For example, components of adipose tissue have double bonds that require a substantially higher energy level than 4 to 5 eV to break. Accordingly, the present invention in its current configuration generally does not ablate or remove such fatty tissue. Of course, factors may be changed such that these double bonds can be broken (e.g., increasing the voltage or changing the electrode configuration to increase the current density at the electrode tips).

In another aspect of the invention, a loop electrode is employed to resect, shape or otherwise remove tissue fragments from the treatment site, and one or more active electrodes are employed to ablate (i.e., break down the tissue by processes including molecular dissociation or disintegration) the non-ablated tissue fragments *in situ*. Once a tissue fragment is cut, partially ablated or resected by the loop electrode, one or more active electrodes will be brought into close proximity to these fragments (either by moving the probe into position, or by drawing the fragments to the active electrodes with a suction lumen). Voltage is applied between the active electrodes and the return electrode to volumetrically remove the fragments through molecular dissociation, as described above. The loop electrode and the active electrodes are preferably electrically isolated from each other such that, for example, current can be limited (passively or actively) or completely interrupted to the loop electrode as the surgeon employs the active electrodes to ablate tissue fragments (and vice versa).

In another aspect of the invention, the loop electrode(s) are employed to ablate tissue using the Coblation® mechanisms described above. In these embodiments, the loop electrode(s) provides a relatively uniform smooth cutting or ablation effect across the tissue. In addition, loop electrodes generally have a larger surface area exposed to electrically conductive fluid (as compared to the smaller active electrodes described above), which increases the rate of ablation of tissue. Preferably, the loop electrode(s) extend a sufficient distance from the electrode support member selected to achieve a desirable ablation rate, while minimizing power dissipation into the surrounding medium (which could cause undesirable thermal damage to surrounding or underlying tissue). In an exemplary embodiment, the loop electrode has a length from one end to the other end of



about 0.5 to 20 mm, usually about 1 to 8 mm. The loop electrode usually extends about 0.25 to 10 mm from the distal end of the support member, preferably about 1 to 4 mm.

The loop electrode(s) may have a variety of cross-sectional shapes.

Electrode shapes according to the present invention can include the use of formed wire (e.g., by drawing round wire through a shaping die) to form electrodes with a variety of cross-sectional shapes, such as square, rectangular, L or V shaped, or the like. Electrode edges may also be created by removing a portion of the elongate metal electrode to reshape the cross-section. For example, material can be removed along the length of a solid or hollow wire electrode to form D or C shaped wires, respectively, with edges facing in the cutting direction. Alternatively, material can be removed at closely spaced intervals along the electrode length to form transverse grooves, slots, threads or the like along the electrodes.

In some embodiments, the loop electrode(s) will have a "non-active" portion or surface to selectively reduce undesirable current flow from the non-active portion or surface into tissue or surrounding electrically conductive liquids (e.g., isotonic saline, blood or blood/non-conducting irrigant mixtures). Preferably, the "non-active" electrode portion will be coated with an electrically insulating material. This can be accomplished, for example, with plasma deposited coatings of an insulating material, thin-film deposition of an insulating material using evaporative or sputtering techniques (e.g.,  $\text{SiO}_2$  or  $\text{Si}_3\text{N}_4$ ), dip coating, or by providing an electrically insulating support member to electrically insulate a portion of the external surface of the electrode. The electrically insulated non-active portion of the active electrode(s) allows the surgeon to selectively resect and/or ablate tissue, while minimizing necrosis or ablation of surrounding non-target tissue or other body structures.

In addition, the loop electrode(s) may comprise a single electrode extending from first and second ends to an insulating support in the shaft, or multiple, electrically isolated electrodes extending around the loop. One or more return electrodes may also be positioned along the loop portion. Further descriptions of these configurations can be found in U.S. Application No. 08/687,792, filed on July 18, 1996 (Docket No. 16238-001600), which as already been incorporated herein by reference.

The electrosurgical probe will comprise a shaft or a handpiece having a proximal end and a distal end which supports one or more active electrode(s). The shaft or handpiece may assume a wide variety of configurations, with the primary purpose being to

mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. The distal portion of the shaft may comprise a flexible material, such as plastics, malleable stainless steel, etc, so that the physician can mold the distal portion into different configurations for different applications. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 0.5 mm and frequently in the range of from about 1 to 10 mm. Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.

For procedures within the nose and joints, the shaft will have a suitable diameter and length to allow the surgeon to reach the target by delivering the probe shaft through an percutaneous opening in the patient (e.g., a portal formed in the joint in arthroscopic surgery, or through one of the patient's nasal passages in FESS). Thus, the shaft will usually have a length in the range of from about 5 to 25 cm, and a diameter in the range of from about 0.5 to 5 mm. For procedures requiring the formation of a small hole or channel in tissue, such as treating swollen turbinates, the shaft diameter will usually be less than 3 mm, preferably less than about 1 mm. Likewise, for procedures in the ear, the shaft should have a length in the range of about 3 to 20 cm, and a diameter of about 0.3 to 5 mm. For procedures in the mouth or upper throat, the shaft will have any suitable length and diameter that would facilitate handling by the surgeon. For procedures in the lower throat, such as laryngectomies, the shaft will be suitably designed to access the larynx. For example, the shaft may be flexible, or have a distal bend to accommodate the bend in the patient's throat. In this regard, the shaft may be a rigid shaft having a specifically designed bend to correspond with the geometry of the mouth and throat, or it may have a flexible distal end, or it may be part of a catheter. In any of these

embodiments, the shaft may also be introduced through rigid or flexible endoscopes. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The current flow path between the active electrode(s) and the return electrode(s) may be generated by submerging the tissue site in an electrically conductive fluid (e.g., a viscous fluid, such as an electrically conductive gel), or by directing an electrically conductive fluid along a fluid path to the target site (i.e., a liquid, such as isotonic saline, or a gas, such as argon). This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid) because the electrically conductive fluid provides a suitable current flow path from the active electrode to the return electrode. A more complete description of an exemplary method of directing electrically conductive fluid between the active and return electrodes is described in parent application Serial No. 08/485,219, filed June 7, 1995 (Attorney Docket No. 16238-000600), previously incorporated herein by reference.

In some procedures, it may also be necessary to retrieve or aspirate the electrically conductive fluid after it has been directed to the target site. For example, in procedures in the nose, mouth or throat, it may be desirable to aspirate the fluid so that it does not flow down the patient's throat. In addition, it may be desirable to aspirate small pieces of tissue that are not completely disintegrated by the high frequency energy, air bubbles, or other fluids at the target site, such as blood, mucus, the gaseous products of ablation, etc. Accordingly, the system of the present invention can include a suction lumen in the probe, or on another instrument, for aspirating fluids from the target site.

In some embodiments, the probe will include one or more aspiration electrode(s) coupled to the distal end of the suction lumen for ablating, or at least reducing the volume of, tissue fragments that are aspirated into the lumen. The aspiration electrode(s) function mainly to inhibit clogging of the lumen that may otherwise occur as larger tissue fragments are drawn therein. The aspiration electrode(s) may be different from the ablation active electrode(s), or the same electrode(s) may serve both functions. In some embodiments, the probe will be designed to use suction force to draw loose tissue, such as synovial tissue to the aspiration or ablation electrode(s) on the probe, which are then energized to ablate the loose tissue.

In other embodiments, the aspiration lumen can be positioned proximal of the active electrodes a sufficient distance such that the aspiration lumen will primarily aspirate air bubbles and body fluids such as blood, mucus, or the like. Such a

configuration allows the electrically conductive fluid to dwell at the target site for a longer period. Consequently, the plasma can be created more aggressively at the target site and the tissue can be treated in a more efficient manner. Additionally, by positioning the aspiration lumen opening somewhat distant from the active electrodes, it may not be necessary to have ablation electrodes at the lumen opening since, in this configuration, tissue fragments will typically not be aspirated through the lumen.

The present invention may use a single active electrode or an electrode array distributed over a contact surface of a probe. In the latter embodiment, the electrode array usually includes a plurality of independently current-limited and/or power-controlled active electrodes to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment. Such unwanted application of electrical energy results from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, electrically conductive gel and the like. The active electrodes may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other active electrodes. Alternatively, the active electrodes may be connected to each other at either the proximal or distal ends of the probe to form a single connector that couples to a power source.

In one configuration, each individual active electrode in the electrode array is electrically insulated from all other active electrodes in the array within the probe and is connected to a power source which is isolated from each of the other active electrodes in the array or to circuitry which limits or interrupts current flow to the active electrode when low resistivity material (*e.g.*, blood, electrically conductive saline irrigant or electrically conductive gel) causes a lower impedance path between the return electrode and the individual active electrode. The isolated power sources for each individual active electrode may be separate power supply circuits having internal impedance characteristics which limit power to the associated active electrode when a low impedance return path is encountered. By way of example, the isolated power source may be a user selectable constant current source. In this embodiment, lower impedance paths will automatically result in lower resistive heating levels since the heating is proportional to the square of the operating current times the impedance. Alternatively, a single power source may be connected to each of the active electrodes through independently actuatable switches, or by independent current limiting elements, such as inductors, capacitors, resistors and/or

combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distal tip of the probe. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode(s) due to oxide layers which form selected active electrodes (e.g., titanium or a resistive coating on the surface of metal, such as platinum).

The tip region of the probe may comprise many independent active electrodes designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the conductive fluid is achieved by connecting each individual active electrode and the return electrode to a power source having independently controlled or current limited channels. The return electrode(s) may comprise a single tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conductive fluid between the active and return electrodes. Alternatively, the probe may comprise an array of return electrodes at the distal tip of the probe (together with the active electrodes) to maintain the electric current at the tip. The application of high frequency voltage between the return electrode(s) and the electrode array results in the generation of high electric field intensities at the distal tips of the active electrodes with conduction of high frequency current from each individual active electrode to the return electrode. The current flow from each individual active electrode to the return electrode(s) is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the surrounding conductive fluid while minimizing energy delivery to surrounding (non-target) tissue.

The application of a high frequency voltage between the return electrode(s) and the active electrode(s) for appropriate time intervals effects cutting, removing, ablating, shaping, contracting or otherwise modifying the target tissue. The tissue volume over which energy is dissipated (*i.e.*, over which a high current density exists) may be precisely controlled, for example, by the use of a multiplicity of small active electrodes whose effective diameters or principal dimensions range from about 5 mm to 0.01 mm, preferably from about 2 mm to 0.05 mm, and more preferably from about 1 mm to 0.1 mm. In these embodiments, electrode areas for both circular and non-circular terminals will have a contact area (per active electrode) below 25 mm<sup>2</sup>, preferably being in the range from 0.0001 mm<sup>2</sup> to 1 mm<sup>2</sup>, and more preferably from 0.005 mm<sup>2</sup> to .5 mm<sup>2</sup>. The circumscribed area of the electrode array is in the range from 0.25 mm<sup>2</sup> to 75 mm<sup>2</sup>,

preferably from 0.5 mm<sup>2</sup> to 40 mm<sup>2</sup>, and will usually include at least two isolated active electrodes, preferably at least five active electrodes, often greater than 10 active electrodes and even 50 or more active electrodes, disposed over the distal contact surfaces on the shaft. The use of small diameter active electrodes increases the electric field intensity and reduces the extent or depth of tissue heating as a consequence of the divergence of current flux lines which emanate from the exposed surface of each active electrode.

The area of the tissue treatment surface can vary widely, and the tissue treatment surface can assume a variety of geometries, with particular areas and geometries being selected for specific applications. Active electrode surfaces can have areas in the range from 0.25 mm<sup>2</sup> to 75 mm<sup>2</sup>, usually being from about 0.5 mm<sup>2</sup> to 40 mm<sup>2</sup>. The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) or active electrode(s) will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical probe shaft (*e.g.*, in the manner of a spatula), facilitating access to certain body structures in endoscopic procedures.

The electrically conductive fluid should have a threshold conductivity to provide a suitable conductive path between the active electrode(s) and the return electrode(s). The electrical conductivity of the fluid (in units of millisiemens per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm.

In some embodiments, the electrode support and the fluid outlet may be recessed from an outer surface of the probe or handpiece to confine the electrically conductive fluid to the region immediately surrounding the electrode support. In addition, the shaft may be shaped so as to form a cavity around the electrode support and the fluid outlet. This helps to assure that the electrically conductive fluid will remain in contact with the active electrode(s) and the return electrode(s) to maintain the conductive path therebetween. In addition, this will help to maintain a vapor or plasma layer between the active electrode(s) and the tissue at the treatment site throughout the procedure, which

reduces the thermal damage that might otherwise occur if the vapor layer were extinguished due to a lack of conductive fluid. Provision of the electrically conductive fluid around the target site also helps to maintain the tissue temperature at desired levels.

The voltage applied between the return electrode(s) and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, preferably being between about 50 kHz and 500 kHz, more preferably less than 350 kHz, and most preferably between about 100 kHz and 200 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 10 volts to 500 volts depending on the active electrode size, the operating frequency and the operation mode of the particular procedure or desired effect on the tissue (i.e., contraction, coagulation or ablation). Typically, the peak-to-peak voltage will be in the range of 10 to 2000 volts, preferably in the range of 20 to 1200 volts and more preferably in the range of about 40 to 800 volts (again, depending on the electrode size, the operating frequency and the operation mode).

As discussed above, the voltage is usually delivered in a series of voltage pulses or alternating current of time varying voltage amplitude with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed at about 10 to 20 Hz). In addition, the duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with pulsed lasers which typically have a duty cycle of about 0.0001%.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from several milliwatts to tens of watts per electrode, depending on the volume of target tissue being heated, and/or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the voltage level according to the specific requirements of a particular FESS procedure, arthroscopic surgery, dermatological procedure, ophthalmic procedures, open surgery or other endoscopic surgery procedure. A description of a suitable power source can be found in U.S. Provisional Patent Application No. 60/062,997 "Systems and Methods for Electrosurgical Tissue and Fluid Coagulation," filed on

October 23, 1997 (Attorney Docket No. 16238-007400), the complete disclosure of which has been incorporated herein by reference.

The power source may be current limited or otherwise controlled so that undesired heating of the target tissue or surrounding (non-target) tissue does not occur. In one embodiment of the present invention, current limiting inductors are placed in series with each independent active electrode, where the inductance of the inductor is in the range of 10uH to 50,000uH, depending on the electrical properties of the target tissue, the desired tissue heating rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual active electrode in contact with a low resistance medium (*e.g.*, saline irrigant or conductive gel), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from the active electrode into the low resistance medium (*e.g.*, saline irrigant or conductive gel).

It should be clearly understood that the invention is not limited to electrically isolated active electrodes, or even to a plurality of active electrodes. For example, the array of active electrodes may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source. The active electrode may have a ball shape (*e.g.*, for tissue vaporization and desiccation), a twizzle shape (for vaporization and needle-like cutting), a spring shape (for rapid tissue debulking and desiccation), a twisted metal shape, an annular or solid tube shape or the like.

Alternatively, the electrode may comprise a plurality of filaments, a rigid or flexible brush electrode (for debulking a tumor, such as a fibroid, bladder tumor or a prostate adenoma), a side-effect brush electrode on a lateral surface of the shaft, a coiled electrode or the like.

In one embodiment, the probe comprises a single active electrode that extends from an insulating member, *e.g.*, ceramic, at the distal end of the probe. The insulating member is preferably a tubular structure that separates the active electrode from a tubular or annular return electrode positioned proximal to the insulating member and the active electrode.



Referring now to Fig. 1, an exemplary electrosurgical system 5 for resection, ablation, coagulation and/or contraction of tissue will now be described in detail. As shown, electrosurgical system 5 generally includes an electrosurgical probe 20 connected to a power supply 10 for providing high frequency voltage to one or more active electrodes and a loop electrode (not shown in Fig. 1) on probe 20. Probe 20 includes a connector housing 44 at its proximal end, which can be removably connected to a probe receptacle 32 of a probe cable 22. The proximal portion of cable 22 has a connector 34 to couple probe 20 to power supply 10. Power supply 10 has an operator controllable voltage level adjustment 38 to change the applied voltage level, which is observable at a voltage level display 40. Power supply 10 also includes one or more foot pedals 24 and a cable 26 which is removably coupled to a receptacle 30 with a cable connector 28. The foot pedal 24 may also include a second pedal (not shown) for remotely adjusting the energy level applied to active electrodes 104 (Fig. 2), and a third pedal (also not shown) for switching between an ablation mode and a coagulation mode.

Figs. 2-5 illustrate an exemplary electrosurgical probe 20 constructed according to the principles of the present invention. As shown in Fig. 2, probe 20 generally includes an elongated shaft 100 which may be flexible or rigid, a handle 204 coupled to the proximal end of shaft 100 and an electrode support member 102 coupled to the distal end of shaft 100. Shaft 100 preferably comprises an electrically conducting material, usually metal, which is selected from the group consisting of tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. Shaft 100 includes an electrically insulating jacket 108, which is typically formed as one or more electrically insulating sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulating jacket over the shaft prevents direct electrical contact between these metal elements and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed electrode could result in unwanted heating of the structure at the point of contact causing necrosis.

Handle 204 typically comprises a plastic material that is easily molded into a suitable shape for handling by the surgeon. As shown in Fig. 3, handle 204 defines an inner cavity 208 that houses electrical connections 250 (discussed below), and provides a suitable interface for connection to an electrical connecting cable 22 (see Fig. 1). As shown in Fig. 5B, the probe will also include a coding resistor 400 having a value selected

to program different output ranges and modes of operation for the power supply. This allows a single power supply to be used with a variety of different probes in different applications (e.g., dermatology, cardiac surgery, neurosurgery, arthroscopy, etc).

Electrode support member 102 extends from the distal end of shaft 100 (usually about 1 to 20 mm), and provides support for a loop electrode 103 and a plurality of electrically isolated active electrodes 104 (see Fig. 4).

As shown in Fig. 3, the distal portion of shaft 100 is preferably bent to improve access to the operative site of the tissue being treated (e.g., contracted).

Electrode support member 102 has a substantially planar tissue treatment surface 212 (see Fig. 4) that is usually at an angle of about 10 to 90 degrees relative to the longitudinal axis of shaft 100, preferably about 10 to 30 degrees and more preferably about 15-18 degrees.

In addition, the distal end of the shaft may have a bevel, as described in commonly-assigned Patent Application Serial No. 08/562,332 filed November 22, 1995 (Attorney Docket 16238- 000710). In alternative embodiments, the distal portion of shaft 100 comprises a flexible material which can be deflected relative to the longitudinal axis of the shaft. Such deflection may be selectively induced by mechanical tension of a pull wire, for example, or by a shape memory wire that expands or contracts by externally applied temperature changes. A more complete description of this embodiment can be found in PCT International Application, U.S. National Phase Serial No. PCT/US94/05168.

The bend in the distal portion of shaft 100 is particularly advantageous in arthroscopic treatment of joint tissue as it allows the surgeon to reach the target tissue within the joint as the shaft 100 extends through a cannula or portal. Of course, it will be recognized that the shaft may have different angles depending on the procedure. For example, a shaft having a 90° bend angle may be particularly useful for accessing tissue located in the back portion of a joint compartment and a shaft having a 10° to 30° bend angle may be useful for accessing tissue near or in the front portion of the joint compartment.

As shown in Fig. 4, loop electrode 103 has first and second ends extending from the electrode support member 102. The first and second ends are coupled to, or integral with, a pair of connectors 300, 302, e.g., wires, that extend through the shaft of the probe to its proximal end for coupling to the high frequency power supply. The loop electrode usually extends about 0.5 to about 10 mm from the distal end of support member 102, preferably about 1 to 2 mm. In the representative embodiment, the loop electrode has

a solid construction with a substantially uniform cross-sectional area, e.g., circular, square, etc. Of course, it will be recognized that the loop or ablation electrode may have a wide variety of cross-sectional shapes, such as annular, square, rectangular, L-shaped, V-shaped, D-shaped, C-shaped, star-shaped and crossed-shaped, as described in commonly-  
5 assigned co-pending Patent Application Serial No. 08/687792. In addition, it should be noted that loop electrode 103 may have a geometry other than that shown in Figs. 2-5, such as a semi-circular loop, a V-shaped loop, a straight wire electrode extending between two support members, and the like. Also, loop electrode may be positioned on a lateral surface of the shaft, or it may extend at a transverse angle from the distal end of the shaft,  
10 depending on the particular surgical procedure.

Loop electrode 103 usually extends further away from the support member than the active electrodes 104 to facilitate resection and ablation of tissue. As discussed below, loop electrode 103 is especially configured for resecting fragments or pieces of tissue, while the active electrodes ablate or cause molecular dissociation or disintegration  
15 of the removed pieces from the fluid environment. In the presently preferred embodiment, the probe will include 3 to 7 active electrodes positioned on either side of the loop electrode. The probe may further include a suction lumen (not shown) for drawing the pieces of tissue toward the active electrodes after they have been removed from the target site by the loop electrode 103.

Referring to Fig. 4, the electrically isolated active electrodes 104 are preferably spaced apart over tissue treatment surface 212 of electrode support member 102. The tissue treatment surface and individual active electrodes 104 will usually have dimensions within the ranges set forth above. In the representative embodiment, the tissue treatment surface 212 has an oval cross-sectional shape with a length L in the range of 1  
25 mm to 20 mm and a width W in the range from 0.3 mm to 7 mm. The oval cross-sectional shape accommodates the bend in the distal portion of shaft 202. The active electrodes 104 preferably extend slightly outward from surface 212, typically by a distance from 0.2 mm to 2. However, it will be understood that electrodes 104 may be flush with this surface, or even recessed, if desired. In one embodiment of the invention, the active electrodes are  
30 axially adjustable relative to the tissue treatment surface so that the surgeon can adjust the distance between the surface and the active electrodes.

In the embodiment shown in Figs. 2-5, probe 20 includes a return electrode 112 for completing the current path between active electrodes 104, loop electrode 103 and

008011 " 5E050460

a high frequency power supply 10 (see Fig. 1). As shown, return electrode 112 preferably comprises an annular exposed region of shaft 102 slightly proximal to tissue treatment surface 212 of electrode support member 102. Return electrode 112 typically has a length of about 0.5 to 10 mm and more preferably about 1 to 10 mm. Return electrode 112 is coupled to a connector 250 that extends to the proximal end of probe 10, where it is suitably connected to power supply 10 (Fig. 1).

As shown in Fig. 2, return electrode 112 is not directly connected to active electrodes 104 and loop electrode 103. To complete a current path from active electrodes 104 or loop electrodes 103 to return electrode 112, electrically conductive fluid (e.g., isotonic saline) is caused to flow therebetween. In the representative embodiment, the electrically conductive fluid is delivered from a fluid delivery element (not shown) that is separate from probe 20. In arthroscopic surgery, for example, the joint cavity will be flooded with isotonic saline and the probe 20 will be introduced into this flooded cavity. Electrically conductive fluid will be continually resupplied to maintain the conduction path between return electrode 112 and active electrodes 104 and loop electrode 103.

In alternative embodiments, the fluid path may be formed in probe 20 by, for example, an inner lumen or an annular gap (not shown) between the return electrode and a tubular support member within shaft 100. This annular gap may be formed near the perimeter of the shaft 100 such that the electrically conductive fluid tends to flow radially inward towards the target site, or it may be formed towards the center of shaft 100 so that the fluid flows radially outward. In both of these embodiments, a fluid source (e.g., a bag of fluid elevated above the surgical site or having a pumping device), is coupled to probe 20 via a fluid supply tube (not shown) that may or may not have a controllable valve. A more complete description of an electrosurgical probe incorporating one or more fluid lumen(s) can be found in commonly assigned, co-pending Patent Application Serial No. 08/485,219, filed on June 7, 1995 (Attorney Docket 16238-0006000), the complete disclosure of which is incorporated herein by reference.

In addition, probe 20 may include an aspiration lumen (not shown) for aspirating excess conductive fluid, other fluids, such as blood, and/or tissue fragments from the target site. The probe may also include one or more aspiration electrode(s), such as those described below in reference to Figs. 8-12, for ablating the aspirated tissue fragments. Alternatively, the aspiration electrode(s) may comprise the active electrodes described above. For example, the probe may have an aspiration lumen with a distal

opening positioned adjacent one or more of the active electrodes at the distal end of the probe. As tissue fragments are drawn into the aspiration lumen, the active electrodes are energized to ablate at least a portion of these fragments to prevent clogging of the lumen.

Referring now to Fig. 6, a surgical kit 300 for resecting and/or ablating tissue within a joint according to the invention will now be described. As shown, surgical kit 300 includes a package 302 for housing a surgical instrument 304, and an instructions for use 306 of instrument 304. Package 302 may comprise any suitable package, such as a box, carton, wrapping, etc. In the exemplary embodiment, kit 300 further includes a sterile wrapping 320 for packaging and storing instrument 304. Instrument 304 includes a shaft 310 having at least one loop electrode 311 and at least one active electrode 312 at its distal end, and at least one connector (not shown) extending from loop electrode 311 and active electrode 312 to the proximal end of shaft 310. The instrument 304 is generally disposable after a single procedure. Instrument 304 may or may not include a return electrode 316.

The instructions for use 306 generally includes the steps of adjusting a voltage level of a high frequency power supply (not shown) to effect resection and/or ablation of tissue at the target site, connecting the surgical instrument 304 to the high frequency power supply, positioning the loop electrode 311 and the active electrode 312 within electrically conductive fluid at or near the tissue at the target site, and activating the power supply. The voltage level is usually about 40 to 400 volts rms for operating frequencies of about 100 to 200 kHz. In a preferred embodiment, the positioning step includes introducing at least a distal portion of the instrument 304 through a portal into a joint.

The present invention is particularly useful for lateral release procedures, or for resecting and ablating a bucket-handle tear of the medial meniscus. In the latter technique, the probe is introduced through a medial port and the volume which surrounds the working end of the probe is filled with an electrically conductive fluid which may, by way of example, be isotonic saline or other biocompatible, electrically conductive irrigant solution. When a voltage is applied between the loop electrode and the return electrode, electrical current flows from the loop electrode, through the irrigant solution to the return electrode. The anterior horn is excised by pressing the exposed portion of the loop electrode into the tear and removing one or more tissue fragments. The displaced fragments are then ablated with the active electrodes as described above.

Through a central patellar splitting approach, the probe is then placed within the joint through the intercondylar notch, and the attached posterior horn insertion is resected by pressing the loop electrode into the attached posterior fragment. The fragment is then removed with the active electrodes and the remnant is checked for stability.

5 Referring now to Fig. 7, an exemplary electrosurgical system 411 for treatment of tissue in 'dry fields' will now be described in detail. Of course, system 411 may also be used in a 'wet field', i.e., the target site is immersed in electrically conductive fluid. However, this system is particularly useful in 'dry fields' where the fluid is preferably delivered through an electrosurgical probe to the target site. As shown,  
10 electrosurgical system 411 generally comprises an electrosurgical handpiece or probe 410 connected to a power supply 428 for providing high frequency voltage to a target site and a fluid source 421 for supplying electrically conductive fluid 450 to probe 410. In addition, electrosurgical system 411 may include an endoscope (not shown) with a fiber optic head light for viewing the surgical site, particularly in sinus procedures or  
15 procedures in the ear or the back of the mouth. The endoscope may be integral with probe 410, or it may be part of a separate instrument. The system 411 may also include a vacuum source (not shown) for coupling to a suction lumen or tube (not shown) in the probe 410 for aspirating the target site.

As shown, probe 410 generally includes a proximal handle 419 and an  
20 elongate shaft 418 having an array 412 of active electrodes 458 at its distal end. A connecting cable 434 has a connector 426 for electrically coupling the active electrodes 458 to power supply 428. The active electrodes 458 are electrically isolated from each other and each of the terminals 458 is connected to an active or passive control network within power supply 428 by means of a plurality of individually insulated conductors (not  
25 shown). A fluid supply tube 415 is connected to a fluid tube 414 of probe 410 for supplying electrically conductive fluid 450 to the target site.

Similar to the above embodiment, power supply 428 has an operator controllable voltage level adjustment 430 to change the applied voltage level, which is observable at a voltage level display 432. Power supply 428 also includes first, second  
30 and third foot pedals 437, 438, 439 and a cable 436 which is removably coupled to power supply 428. The foot pedals 437, 438, 439 allow the surgeon to remotely adjust the energy level applied to active electrodes 458. In an exemplary embodiment, first foot pedal 437 is used to place the power supply into the ablation mode and second foot pedal

00801T 55060260  
09709035 110800

438 places power supply 428 into the "coagulation" mode. The third foot pedal 439 allows the user to adjust the voltage level within the "ablation" mode. In the ablation mode, a sufficient voltage is applied to the active electrodes to establish the requisite conditions for molecular dissociation of the tissue (i.e., vaporizing a portion of the electrically conductive fluid, ionizing charged particles within the vapor layer, and accelerating these charged particles against the tissue). As discussed above, the requisite voltage level for ablation will vary depending on the number, size, shape and spacing of the electrodes, the distance to which the electrodes extend from the support member, etc. Once the surgeon places the power supply in the ablation mode, voltage level adjustment 430 or third foot pedal 439 may be used to adjust the voltage level to adjust the degree or aggressiveness of the ablation.

Of course, it will be recognized that the voltage and modality of the power supply may be controlled by other input devices. However, applicant has found that foot pedals are convenient methods of controlling the power supply while manipulating the probe during a surgical procedure.

In the coagulation mode, the power supply 428 applies a low enough voltage to the active electrodes (or the coagulation electrode) to avoid vaporization of the electrically conductive fluid and subsequent molecular dissociation of the tissue. The surgeon may automatically toggle the power supply between the ablation and coagulation modes by alternately stepping on foot pedals 437, 438, respectively. This allows the surgeon to quickly move between coagulation and ablation *in situ*, without having to remove his/her concentration from the surgical field or without having to request an assistant to switch the power supply. By way of example, as the surgeon is sculpting soft tissue in the ablation mode, the probe typically will simultaneously seal and/or coagulate small severed vessels within the tissue. However, larger vessels, or vessels with high fluid pressures (e.g., arterial vessels) may not be sealed in the ablation mode. Accordingly, the surgeon can simply actuate foot pedal 438, automatically lowering the voltage level below the threshold level for ablation, and apply sufficient pressure onto the severed vessel for a sufficient period of time to seal and/or coagulate the vessel. After this is completed, the surgeon may quickly move back into the ablation mode by actuating foot pedal 437. A specific design of a suitable power supply for use with the present invention can be found in Provisional Patent Application No. 60/062,997 filed October 23, 1997 (Attorney Docket No. 16238-007400), previously incorporated herein by reference.

09709035 "110800

Figs. 8-10 illustrate an exemplary electrosurgical probe 490 constructed according to the principles of the present invention. As shown in Fig. 8, probe 490 generally includes an elongated shaft 500 which may be flexible or rigid, a handle 604 coupled to the proximal end of shaft 500 and an electrode support member 502 coupled to the distal end of shaft 500. Shaft 500 preferably includes a bend 501 that allows the distal section of shaft 500 to be offset from the proximal section and handle 604. This offset facilitates procedures that require an endoscope, such as FESS, because the endoscope can, for example, be introduced through the same nasal passage as the shaft 500 without interference between handle 604 and the eyepiece of the endoscope (see Fig. 16). In one embodiment, shaft 500 preferably comprises a plastic material that is easily molded into a suitable shape.

In an alternative embodiment (not shown), shaft 500 comprises an electrically conducting material, usually metal, which is selected from the group comprising tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. In this embodiment, shaft 500 includes an electrically insulating jacket 508, which is typically formed as one or more electrically insulating sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulating jacket over the shaft prevents direct electrical contact between these metal elements and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (*e.g.*, tendon) and an exposed electrode could result in unwanted heating and necrosis of the structure at the point of contact.

Handle 604 typically comprises a plastic material that is easily molded into a suitable shape for handling by the surgeon. Handle 604 defines an inner cavity (not shown) that houses the electrical connections 650 (Fig. 10), and provides a suitable interface for connection to an electrical connecting cable 422 (see Fig. 7). Electrode support member 502 extends from the distal end of shaft 500 (usually about 1 to 20 mm), and provides support for a plurality of electrically isolated active electrodes 504 (see Fig. 9). As shown in Fig. 8, a fluid tube 633 extends through an opening in handle 604, and includes a connector 635 for connection to a fluid supply source, for supplying electrically conductive fluid to the target site. Depending on the configuration of the distal surface of shaft 500, fluid tube 633 may extend through a single lumen (not shown) in shaft 500, or it may be coupled to a plurality of lumens (also not shown) that extend through shaft 500 to a



plurality of openings at its distal end. In the representative embodiment, fluid tube 633 extends along the exterior of shaft 500 to a point just proximal of return electrode 512 (see Fig. 9). In this embodiment, the fluid is directed through an opening 637 past return electrode 512 to the active electrodes 504. Probe 490 may also include a valve 417 (Fig. 8) or equivalent structure for controlling the flow rate of the electrically conductive fluid to the target site.

As shown in Fig. 8, the distal portion of shaft 500 is preferably bent to improve access to the operative site of the tissue being treated. Electrode support member 502 has a substantially planar tissue treatment surface 612 that is usually at an angle of about 10 to 90 degrees relative to the longitudinal axis of shaft 600, preferably about 30 to 60 degrees and more preferably about 45 degrees. In alternative embodiments, the distal portion of shaft 500 comprises a flexible material which can be deflected relative to the longitudinal axis of the shaft. Such deflection may be selectively induced by mechanical tension of a pull wire, for example, or by a shape memory wire that expands or contracts by externally applied temperature changes. A more complete description of this embodiment can be found in PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994 (Attorney Docket 16238-000440), now U.S. Patent No. 5,697,909, the complete disclosure of which has is incorporated herein by reference.

The bend in the distal portion of shaft 500 is particularly advantageous in the treatment of sinus tissue as it allows the surgeon to reach the target tissue within the nose as the shaft 500 extends through the nasal passage. Of course, it will be recognized that the shaft may have different angles depending on the procedure. For example, a shaft having a 90° bend angle may be particularly useful for accessing tissue located in the back portion of the mouth and a shaft having a 10° to 30° bend angle may be useful for accessing tissue near or in the front portion of the mouth or nose

In the embodiment shown in Figs. 8-10, probe 490 includes a return electrode 512 for completing the current path between active electrodes 504 and a high frequency power supply (e.g., power supply 428, Fig. 8). As shown, return electrode 512 preferably comprises an annular conductive band coupled to the distal end of shaft 500 slightly proximal to tissue treatment surface 612 of electrode support member 502, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm from support member

502. Return electrode 512 is coupled to a connector 658 that extends to the proximal end of probe 409, where it is suitably connected to power supply 428 (Fig. 7).

As shown in Fig. 8, return electrode 512 is not directly connected to active electrodes 504. To complete this current path so that active electrodes 504 are electrically connected to return electrode 512, electrically conductive fluid (e.g., isotonic saline) is caused to flow therebetween. In the representative embodiment, the electrically conductive fluid is delivered through fluid tube 633 to opening 637, as described above. Alternatively, the fluid may be delivered by a fluid delivery element (not shown) that is separate from probe 490. In arthroscopic surgery, for example, the joint cavity will be flooded with isotonic saline and the probe 490 will be introduced into this flooded cavity. Electrically conductive fluid will be continually resupplied to maintain the conduction path between return electrode 512 and active electrodes 504.

In alternative embodiments, the fluid path may be formed in probe 490 by, for example, an inner lumen or an annular gap between the return electrode and a tubular support member within shaft 500. This annular gap may be formed near the perimeter of the shaft 500 such that the electrically conductive fluid tends to flow radially inward towards the target site, or it may be formed towards the center of shaft 500 so that the fluid flows radially outward. In both of these embodiments, a fluid source (e.g., a bag of fluid elevated above the surgical site or having a pumping device), is coupled to probe 490 via a fluid supply tube (not shown) that may or may not have a controllable valve. A more complete description of an electrosurgical probe incorporating one or more fluid lumen(s) can be found in parent Patent Application Serial No. 08/485,219, filed on June 7, 1995 (Attorney Docket 16238-006000), the complete disclosure of which is incorporated herein by reference.

Referring to Fig. 9, the electrically isolated active electrodes 504 are spaced apart over tissue treatment surface 612 of electrode support member 502. The tissue treatment surface and individual active electrodes 504 will usually have dimensions within the ranges set forth above. As shown, the probe includes a single, larger opening 609 in the center of tissue treatment surface 612, and a plurality of active electrodes (e.g., about 3-15) around the perimeter of surface 612 (see Fig. 9). Alternatively, the probe may include a single, annular, or partially annular, active electrode at the perimeter of the tissue treatment surface. The central opening 609 is coupled to a suction lumen (not shown) within shaft 500 and a suction tube 611 (Fig. 8) for aspirating tissue, fluids and/or

gases from the target site. In this embodiment, the electrically conductive fluid generally flows radially inward past active electrodes 504 and then back through the opening 609. Aspirating the electrically conductive fluid during surgery allows the surgeon to see the target site, and it prevents the fluid from flowing into the patient's body, e.g., through the sinus passages, down the patient's throat or into the ear canal.

As shown, one or more of the active electrodes 504 comprise loop electrodes 540 that extend across distal opening 609 of the suction lumen within shaft 500.

In the representative embodiment, two of the active electrodes 504 comprise loop electrodes 540 that cross over the distal opening 609. Of course, it will be recognized that a variety of different configurations are possible, such as a single loop electrode, or multiple loop electrodes having different configurations than shown. In addition, the electrodes may have shapes other than loops, such as the coiled configurations shown in Figs. 11 and 12. Alternatively, the electrodes may be formed within the suction lumen proximal to the distal opening 609, as shown in Fig. 13. The main function of loop electrodes 540 is to ablate portions of tissue that are drawn into the suction lumen to prevent clogging of the lumen.

Loop electrodes 540 are electrically isolated from the other active electrodes 504, which can be referred to hereinafter as the ablation electrodes 504. Loop electrodes 540 may or may not be electrically isolated from each other. Loop electrodes 540 will usually extend only about 0.05 to 4 mm, preferably about 0.1 to 1 mm from the tissue treatment surface of electrode support member 504.

Of course, it will be recognized that the distal tip of the probe may have a variety of different configurations. For example, the probe may include a plurality of openings 609 around the outer perimeter of tissue treatment surface 612. In this embodiment, the active electrodes 504 extend from the center of tissue treatment surface 612 radially inward from openings 609. The openings are suitably coupled to fluid tube 633 for delivering electrically conductive fluid to the target site, and a suction tube 611 for aspirating the fluid after it has completed the conductive path between the return electrode 512 and the active electrodes 504. In this embodiment, the ablation active electrodes 504 are close enough to openings 609 to ablate most of the large tissue fragments that are drawn into these openings.

Fig. 10 illustrates the electrical connections 650 within handle 604 for coupling active electrodes 504 and return electrode 512 to the power supply 428. As

shown, a plurality of wires 652 extend through shaft 500 to couple terminals 504 to a plurality of pins 654, which are plugged into a connector block 656 for coupling to a connecting cable 422 (Fig. 7). Similarly, return electrode 512 is coupled to connector block 656 via a wire 658 and a plug 660.

5 In use, the distal portion of probe 490 is introduced to the target site (either endoscopically, through an open procedure, or directly onto the patient's skin) and active electrodes 504 are positioned adjacent to tissue at the target site. Electrically conductive fluid is delivered through tube 633 and opening 637 to the tissue. The fluid flows past the return electrode 512 to the active electrodes 504 at the distal end of the shaft. The rate of  
10 fluid flow is controlled with valve 417 (Fig. 7) such that the zone between the tissue and electrode support 502 is constantly immersed in the fluid. The power supply 428 is then turned on and adjusted such that a high frequency voltage difference is applied between active electrodes 504 and return electrode 512. The electrically conductive fluid provides the conduction path between active electrodes 504 and the return electrode 512.

15 In the representative embodiment, the high frequency voltage is sufficient to convert the electrically conductive fluid (not shown) between the target tissue and active electrodes 504 into an ionized vapor layer or plasma (not shown). As a result of the applied voltage difference between active electrode(s) 504 and the target tissue (i.e., the voltage gradient across the plasma layer), charged particles in the plasma (e.g., electrons)  
20 are accelerated towards the tissue. At sufficiently high voltage differences, these charged particles gain sufficient energy to cause dissociation of the molecular bonds within tissue structures. This molecular dissociation is accompanied by the volumetric removal (i.e., ablative sublimation) of tissue and the production of low molecular weight gases, such as oxygen, nitrogen, carbon dioxide, hydrogen and methane. The short range of the  
25 accelerated charged particles within the tissue confines the molecular dissociation process to the surface layer to minimize damage and necrosis to the underlying tissue.

During the process, the gases will be aspirated through opening 609 and suction tube 611 to a vacuum source or collection reservoir (not shown). In addition, excess electrically conductive fluid and other fluids (e.g., blood) will be aspirated from the  
30 target site to facilitate the surgeon's view. Applicant has also found that tissue fragments are also aspirated through opening 609 into suction lumen and tube 611 during the procedure. These tissue fragments are ablated or dissociated with loop electrodes 540 with a similar mechanism described above. Namely, as electrically conductive fluid and tissue

fragments are aspirated towards loop electrodes 540, these electrodes are activated so that a high frequency voltage is applied to loop electrodes 540 and return electrode 512 (of course, the probe may include a different, separate return electrode for this purpose). The voltage is sufficient to vaporize the fluid, and create a plasma layer between loop  
5 electrodes 540 and the tissue fragments so that portions of the tissue fragments are ablated or removed. This reduces the volume of the tissue fragments as they pass through suction lumen to minimize clogging of the lumen.

In addition, the present invention is particularly useful for removing elastic tissue, such as the synovial tissue found in joints. In arthroscopic procedures, this elastic  
10 synovial tissue tends to move away from instruments within the conductive fluid, making it difficult for conventional instruments to remove this tissue. With the present invention, the probe is moved adjacent the target synovial tissue, and the vacuum source is activated to draw the synovial tissue towards the distal end of the probe. The aspiration and/or active electrodes are then energized to ablate this tissue. This allows the surgeon to  
15 quickly and precisely ablate elastic tissue with minimal thermal damage to the treatment site.

In one embodiment, loop electrodes 540 are electrically isolated from the other active electrodes 504, and electrodes 540 must be separately activated by power supply 428. In other embodiments, loop electrodes 540 will be activated at the same time  
20 that active electrodes 504 are activated. In this case, applicant has found that the plasma layer typically forms when tissue is drawn adjacent to loop electrodes 540.

Referring now to Figs. 11 and 12, alternative embodiments for aspiration electrodes will now be described. As shown in Fig. 11, the aspiration electrodes may comprise a pair of coiled electrodes 550 that extend across distal opening 609 of the  
25 suction lumen. The larger surface area of the coiled electrodes 550 usually increases the effectiveness of the electrodes 550 in ablating tissue fragments passing through opening 609. In Fig. 12, the aspiration electrode comprises a single coiled electrode 552 passing across the distal opening 609 of suction lumen. This single electrode 552 may be sufficient to inhibit clogging of the suction lumen. Alternatively, the aspiration electrodes  
30 may be positioned within the suction lumen proximal to the distal opening 609. Preferably, these electrodes are close to opening 609 so that tissue does not clog the opening 609 before it reaches electrode(s) 554. In this embodiment, a separate return

electrode 556 may be provided within the suction lumen to confine the electric currents therein.

Referring to Fig. 13, another embodiment of the present invention incorporates an aspiration electrode 560 within the aspiration lumen 562 of the probe. As shown, the electrode 560 is positioned just proximal of distal opening 609 so that the tissue fragments are ablated as they enter lumen 562. In the representative embodiment, the aspiration electrode 560 comprises a loop electrode that extends across the aspiration lumen 562. However, it will be recognized that many other configurations are possible. In this embodiment, the return electrode 564 is located on the exterior of the probe, as in the previously described embodiments. Alternatively, the return electrode(s) may be located within the aspiration lumen 562 with the aspiration electrode 560. For example, the inner insulating coating may be exposed at portions within the lumen 562 to provide a conductive path between this exposed portion of return electrode 564 and the aspiration electrode 560. The latter embodiment has the advantage of confining the electric currents to within the aspiration lumen. In addition, in dry fields in which the conductive fluid is delivered to the target site, it is usually easier to maintain a conductive fluid path between the active and return electrodes in the latter embodiment because the conductive fluid is aspirated through the aspiration lumen 562 along with the tissue fragments.

Figs. 14-17 illustrate a method for treating nasal or sinus blockages, e.g., chronic sinusitis, according to the present invention. In these procedures, the polyps, turbinates or other sinus tissue may be ablated or reduced (e.g., by tissue contraction) to clear the blockage and/or enlarge the sinus cavity to reestablish normal sinus function. For example, in chronic rhinitis, which is a collective term for chronic irritation or inflammation of the nasal mucosa with hypertrophy of the nasal mucosa, the inferior turbinate may be reduced by ablation or contraction. Alternatively, a turbinectomy or mucotomy may be performed by removing a strip of tissue from the lower edge of the inferior turbinate to reduce the volume of the turbinate. For treating nasal polypi, which comprises benign pedicled or sessile masses of nasal or sinus mucosa caused by inflammation, the nasal polypi may be contracted or shrunk, or ablated by the method of the present invention. For treating severe sinusitis, a frontal sinus operation may be performed to introduce the electrosurgical probe to the site of blockage. The present invention may also be used to treat diseases of the septum, e.g., ablating or resecting portions of the septum for removal, straightening or reimplantation of the septum.

The present invention is particularly useful in functional endoscopic sinus surgery (FESS) in the treatment of sinus disease. In contrast to prior art microdebridors, the electrosurgical probe of the present invention effects hemostasis of severed blood vessels, and allows the surgeon to precisely remove tissue with minimal or no damage to surrounding tissue, bone, cartilage or nerves. By way of example and not limitation, the present invention may be used for the following procedures: (1) uncinectomy or medial displacement or removal of portions of the middle turbinate; (2) maxillary, sphenoid or ethmoid sinusotomies or enlargement of the natural ostium of the maxillary, sphenoid, or ethmoid sinuses, respectively; (3) frontal recess dissections, in which polypoid or granulation tissue are removed; (4) polypectomies, wherein polypoid tissue is removed in the case of severe nasal polyposis; (5) concha bullosa resections or the thinning of polypoid middle turbinate; (6) septoplasty; and the like.

Figures 14-17 schematically illustrate an endoscopic sinus surgery (FESS) procedure according to the present invention. As shown in Fig. 14, an endoscope 700 is first introduced through one of the nasal passages 701 to allow the surgeon to view the target site, e.g., the sinus cavities. As shown, the endoscope 700 will usually comprise a thin metal tube 702 with a lens (not shown) at the distal end 704, and an eyepiece 706 at the proximal end 708. As shown in Fig. 8, the probe shaft 500 has a bend 501 to facilitate use of both the endoscope and the probe 490 in the same nasal passage (i.e., the handles of the two instruments do not interfere with each other in this embodiment). Alternatively, the endoscope may be introduced transorally through the inferior soft palate to view the nasopharynx. Suitable nasal endoscopes for use with the present invention are described in U.S. Patent Nos. 4,517,962, 4,844,052, 4,881,523 and 5,167,220, the complete disclosures of which are incorporated herein by reference for all purposes.

Alternatively, the endoscope 700 may include a sheath (not shown) having an inner lumen for receiving the electrosurgical probe shaft 500. In this embodiment, the shaft 500 will extend through the inner lumen to a distal opening in the endoscope. The shaft will include suitable proximal controls for manipulation of its distal end during the surgical procedure.

As shown in Fig. 15, the distal end of probe 490 is introduced through nasal passage 701 into the nasal cavity 703 (endoscope 700 is not shown in Fig. 15). Depending on the location of the blockage, the active electrodes 504 will be positioned adjacent the blockage in the nasal cavity 703, or in one of the paranasal sinuses 705, 707.

09709035 410800

Note that only the frontal sinus 705 and the sphenoidal sinus 707 are shown in Fig. 15, but the procedure is also applicable to the ethmoidal and maxillary sinuses. Once the surgeon has reached the point of major blockage, electrically conductive fluid is delivered through tube 633 and opening 637 to the tissue (see Fig. 8). The fluid flows past the return electrode 512 to the active electrodes 504 at the distal end of the shaft. The rate of fluid flow is controlled by valve 417 (Fig. 8) such that the zone between the tissue and electrode support 502 is constantly immersed in the fluid. The power supply 428 is then turned on and adjusted such that a high frequency voltage difference is applied between active electrodes 504 and return electrode 512. The electrically conductive fluid provides the conduction path between active electrodes 504 and the return electrode 512.

Figs. 16A and 16B illustrate the removal of sinus tissue in more detail. As shown, the high frequency voltage is sufficient to convert the electrically conductive fluid (not shown) between the target tissue 702 and active electrode(s) 504 into an ionized vapor layer 712 or plasma. As a result of the applied voltage difference between active electrode(s) 504 (or active electrode 458) and the target tissue 702 (i.e., the voltage gradient across the plasma layer 712), charged particles 715 in the plasma (e.g., electrons) are accelerated. At sufficiently high voltage differences, these charged particles 715 gain sufficient energy to cause dissociation of the molecular bonds within tissue structures in contact with the plasma field. This molecular dissociation is accompanied by the volumetric removal (i.e., ablative sublimation) of tissue and the production of low molecular weight gases 714, such as oxygen, nitrogen, carbon dioxide, hydrogen and methane. The short range of the accelerated charged particles 715 within the tissue confines the molecular dissociation process to the surface layer to minimize damage and necrosis to the underlying tissue 720.

During the process, the gases 714 will be aspirated through opening 609 and suction tube 611 to a vacuum source. In addition, excess electrically conductive fluid, and other fluids (e.g., blood) will be aspirated from the target site 700 to facilitate the surgeon's view. During ablation of the tissue, the residual heat generated by the current flux lines, will usually be sufficient to coagulate any severed blood vessels at the site. Typically, the temperature of the treated tissue is less than 150°C. If the residual heat is not sufficient to coagulate severed blood vessels, the surgeon may switch the power supply 428 into the coagulation mode by lowering the voltage to a level below the threshold for fluid vaporization, as discussed above. This simultaneous hemostasis results in less



bleeding and facilitates the surgeon's ability to perform the procedure. Once the blockage has been removed, aeration and drainage are reestablished to allow the sinuses to heal and return to their normal function.

Figs. 18-22 illustrate another embodiment of the present invention. As shown in Fig. 18, an electrosurgical probe 800 includes an elongated shaft 801 which may be flexible or rigid, a handle 804 coupled to the proximal end of shaft 801 and an electrode support member 802 coupled to the distal end of shaft 801. As in previous embodiments, probe 800 includes an active loop electrode 803 (e.g., Fig. 20) and a return electrode 812 (not shown), the latter spaced proximally from active loop electrode 803. The probe 800 further includes a suction lumen 820 (Fig. 19) for aspirating excess fluids, bubbles, tissue fragments, and/or products of ablation from the target site. As shown in Figs. 19 and 22, suction lumen 820 extends through support member 802 to a distal opening 822, and extends through shaft 801 and handle 804 to an external connector 824 for coupling to a vacuum source. Typically, the vacuum source is a standard hospital pump that provides suction pressure to connector 824 and lumen 820.

As shown in Fig. 19, handle 804 defines an inner cavity 808 that houses the electrical connections 850 (discussed above), and provides a suitable interface for connection to an electrical connecting cable 22 (see Fig. 1). As shown in Fig. 21, the probe will also include a coding resistor 860 having a value selected to program different output ranges and modes of operation for the power supply. This allows a single power supply to be used with a variety of different probes in different applications (e.g., dermatology, cardiac surgery, neurosurgery, arthroscopy, etc).

Electrode support member 802 extends from the distal end of shaft 801 (usually about 1 to 20 mm), and provides support for loop electrode 803 and a ring electrode 804 (see Fig. 22). As shown in Fig. 20, loop electrode 803 has first and second ends extending from the electrode support member 802. The first and second ends are each coupled to, or integral with, one or more connectors, e.g., wires (not shown), that extend through the shaft of the probe to its proximal end for coupling to the high frequency power supply. The loop electrode usually extends about 0.5 to about 10 mm from the distal end of support member, preferably about 1 to 2 mm. Loop electrode 803 usually extends further away from the support member than the ring electrode 804 to facilitate ablation of tissue. As discussed below, loop electrode 803 is especially configured for

tissue ablation, while the ring electrode 804 ablates tissue fragments that are aspirated into suction lumen 820.

Referring to Fig. 22, ring electrode 804 preferably comprises a tungsten or titanium wire having two ends 830, 832 coupled to electrical connectors (not shown) within support member 802. The wire is bent to form one-half of a figure eight, thereby forming a ring positioned over opening 822 of suction lumen 820. This ring inhibits passage of tissue fragments large enough to clog suction lumen 820. Moreover, voltages applied between ring electrode 804 and return electrode 812 provide sufficient energy to ablate these tissue fragments into smaller fragments that are then aspirated through lumen 820. In a presently preferred embodiment, ring electrode 804 and loop electrode 803 are electrically isolated from each other. However, electrodes 804, 803 may be electrically coupled to each other in some applications.

Figs. 25-31 illustrate another embodiment of the present invention including an electrosurgical probe 900 incorporating an active screen electrode 902. As shown in Fig. 25, probe 900 includes an elongated shaft 904 which may be flexible or rigid, a handle 906 coupled to the proximal end of shaft 904 and an electrode support member 908 coupled to the distal end of shaft 904. Probe 900 further includes an active screen electrode 902 and a return electrode 910 spaced proximally from active screen electrode 902. In this embodiment, active screen electrode 902 and support member 908 are configured such that the active electrode 902 is positioned on a lateral side of the shaft 904 (e.g., 90 degrees from the shaft axis) to allow the physician to access tissue that is offset from the axis of the portal or arthroscopic opening into the joint cavity in which the shaft 904 passes during the procedure. To accomplish this, probe 900 includes an electrically insulating cap 920 coupled to the distal end of shaft 904 and having a lateral opening 922 for receiving support member 908 and screen electrode 902.

The probe 900 further includes a suction connection tube 914 for coupling to a source of vacuum, and an inner suction lumen 912 (Fig. 26) for aspirating excess fluids, tissue fragments, and/or products of ablation (e.g., bubbles) from the target site. In addition, suction lumen 912 allows the surgeon to draw loose tissue, e.g., synovial tissue, towards the screen electrode 902, as discussed above. Typically, the vacuum source is a standard hospital pump that provides suction pressure to connection tube 914 and lumen 912. However, a pump may also be incorporated into the high frequency power supply. As shown in Figs. 26, 27 and 30, internal suction lumen 912, which preferably comprises

peek tubing, extends from connection tube 914 in handle 906, through shaft 904 to an axial opening 916 in support member 908, through support member 908 to a lateral opening 918. Lateral opening 918 contacts screen electrode 902, which includes a plurality of holes 924 (Fig. 28) for allowing aspiration therethrough, as discussed below.

5 As shown in Fig. 26, handle 906 defines an inner cavity 926 that houses the electrical connections 928 (discussed above), and provides a suitable interface for connection to an electrical connecting cable 22 (see Fig. 1). As shown in Fig. 29, the probe will also include a coding resistor 930 having a value selected to program different output ranges and modes of operation for the power supply. This allows a single power  
10 supply to be used with a variety of different probes in different applications (e.g., dermatology, cardiac surgery, neurosurgery, arthroscopy, etc).

Referring to Fig. 29, electrode support member 908 preferably comprises an inorganic material, such as glass, ceramic, silicon nitride, alumina or the like, that has been formed with lateral and axial openings 918, 916 for suction, and with one or more  
15 smaller holes 930 for receiving electrical connectors 932. In the representative embodiment, support member 908 has a cylindrical shape for supporting a circular screen electrode 902. Of course, screen electrode 902 may have a variety of different shapes, such as the rectangular shape shown in Fig. 31, which may change the associated shape of support member 908. As shown in Fig. 27, electrical connectors 932 extend from  
20 connections 928, through shaft 904 and holes 930 in support member 908 to screen electrode 902 to couple the active electrode 902 to a high frequency power supply. In the representative embodiment, screen electrode 902 is mounted to support member 908 by ball wires 934 that extend through holes 936 in screen electrode 902 and holes 930 in support member 908. Ball wires 934 function to electrically couple the screen 902 to  
25 connectors 932 and to secure the screen 902 onto the support member 908. Of course, a variety of other methods may be used to accomplish these functions, such as nailhead wires, adhesive and standard wires, a channel in the support member, etc.

The screen electrode 902 will comprise a conductive material, such as tungsten, titanium, molybdenum, stainless steel, aluminum, gold, copper or the like. In  
30 some embodiments, it may be advantageous to construct the active and return electrodes of the same material to eliminate the possibility of DC currents being created by dissimilar metal electrodes. Screen electrode 902 will usually have a diameter in the range of about 0.5 to 8 mm, preferably about 1 to 4 mm, and a thickness of about 0.05 to about 2.5 mm,

preferably about 0.1 to 1 mm. Electrode 902 will comprise a plurality of holes 924 having sizes that may vary depending on the particular application and the number of holes (usually from one to 50 holes, and preferably about 3 to 20 holes). Holes 924 will typically be large enough to allow ablated tissue fragments to pass through into suction lumen 912, typically being about 2 to 30 mils in diameter, preferably about 5 to 20 mils in diameter. In some applications, it may be desirable to only aspirate fluid and the gaseous products of ablation (e.g., bubbles) so that the holes may be much smaller, e.g., on the order of less than 10 mils, often less than 5 mils.

In the representative embodiment, probe 900 is manufactured as follows:

screen electrode 902 is placed on support member 908 so that holes 924 are lined up with holes 930. One or more ball wires 934 are inserted through these holes, and a small amount of adhesive (e.g., epotek) is placed around the outer face of support member 908. The ball wires 934 are then pulled until screen 902 is flush with support member 908, and the entire sub-assembly is cured in an oven or other suitable heating mechanism. The electrode-support member sub-assembly is then inserted through the lateral opening in cap 920 and adhesive is applied to the peek tubing suction lumen 912. The suction lumen 912 is then placed through axial hole 916 in support member 908 and this sub-assembly is cured. The return electrode 910 (which is typically the exposed portion of shaft 904) is then adhered to cap 920.

Another advantage of the present invention is the ability to precisely ablate layers of sinus tissue without causing necrosis or thermal damage to the underlying and surrounding tissues, nerves (e.g., the optic nerve) or bone. In addition, the voltage can be controlled so that the energy directed to the target site is insufficient to ablate bone or adipose tissue (which generally has a higher impedance than the target sinus tissue). In this manner, the surgeon can literally clean the tissue off the bone, without ablating or otherwise effecting significant damage to the bone.

Methods for treating air passage disorders according to the present invention will now be described. In these embodiments, an electrosurgical probe such as one described above can be used to ablate targeted masses including, but not limited to, the tongue, tonsils, turbinates, soft palate tissues (e.g., the uvula), hard tissue and mucosal tissue. In one embodiment, selected portions of the tongue 714 are removed to treat sleep apnea. In this method, the distal end of an electrosurgical probe 490 is introduced into the patient's mouth 710, as shown in Fig. 17. An endoscope (not shown), or other type of

viewing device, may also be introduced, or partially introduced, into the mouth 710 to allow the surgeon to view the procedure (the viewing device may be integral with, or separate from, the electrosurgical probe). The active electrodes 504 are positioned adjacent to or against the back surface 716 of the tongue 714, and electrically conductive fluid is delivered to the target site, as described above. The power supply 428 is then activated to remove selected portions of the back of the tongue 714, as described above, without damaging sensitive structures, such as nerves, and the bottom portion of the tongue 714.

In another embodiment, the electrosurgical probe of the present invention can be used to ablate and/or contract soft palate tissue to treat snoring disorders. In particular, the probe is used to ablate or shrink sections of the uvula 720 without causing unwanted tissue damage under and around the selected sections of tissue. For tissue contraction, a sufficient voltage difference is applied between the active electrodes 504 and the return electrode 512 to elevate the uvula tissue temperature from normal body temperatures (e.g., 37°C) to temperatures in the range of 45°C to 90°C, preferably in the range from 60°C to 70°C. This temperature elevation causes contraction of the collagen connective fibers within the uvula tissue.

In addition to the above procedures, the system and method of the present invention may be used for treating a variety of disorders in the mouth 710, pharynx 730, larynx 735, hypopharynx, trachea 740, esophagus 750 and the neck 760. For example, tonsillar hyperplasia or other tonsil disorders may be treated with a tonsillectomy by partially ablating the lymphoepithelial tissue. This procedure is usually carried out under intubation anesthesia with the head extended. An incision is made in the anterior faucial pillar, and the connective tissue layer between the tonsillar parenchyma and the pharyngeal constrictor muscles is demonstrated. The incision may be made with conventional scalpels, or with the electrosurgical probe of the present invention. The tonsil is then freed by ablating through the upper pole to the base of the tongue, preserving the faucial pillars. The probe ablates the tissue, while providing simultaneous hemostasis of severed blood vessels in the region. Similarly, adenoid hyperplasia, or nasal obstruction leading to mouth breathing difficulty, can be treated in an adenoidectomy by separating (e.g., resecting or ablating) the adenoid from the base of the nasopharynx.

Other pharyngeal disorders can be treated according to the present invention. For example, hypopharyngeal diverticulum involves small pouches that form

within the esophagus immediately above the esophageal opening. The sac of the pouch may be removed endoscopically according to the present invention by introducing a rigid esophagoscope, and isolating the sac of the pouch. The cricopharyngeus muscle is then divided, and the pouch is ablated according to the present invention. Tumors within the mouth and pharynx, such as hemangiomas, lymphangiomas, papillomas, lingual thyroid tumors, or malignant tumors, may also be removed according to the present invention.

Other procedures of the present invention include removal of vocal cord polyps and lesions and partial or total laryngectomies. In the latter procedure, the entire larynx is removed from the base of the tongue to the trachea, if necessary with removal of parts of the tongue, the pharynx, the trachea and the thyroid gland.

Tracheal stenosis may also be treated according to the present invention. Acute and chronic stenoses within the wall of the trachea may cause coughing, cyanosis and choking.

Fig. 23 schematically illustrates a lipectomy procedure in the abdomen according to the present invention. In a conventional liposuction procedure according to the prior art, multiple incisions are made to allow cross-tunneling, and the surgeon will manipulate the suction cannula in a linear piston-like motion during suction to remove the adipose tissue to avoid clogging of the cannula, and to facilitate separation of the fatty tissue from the remaining tissue. The present invention mostly solves these two problems and, therefore, minimizes the need for the surgeon to manipulate the probe in such a fashion.

Liposuction in the abdomen, lower torso and thighs according to the present invention removes the subcutaneous fat in these regions while leaving the fascial, neurovascular and lymphatic network intact or only mildly compromised. As shown, access incisions 1200 are typically positioned in natural skin creases remote from the areas to be liposuctioned. As shown in Fig. 23, the distal portion (not shown) of an electrosurgical instrument 1202 is introduced through one or more of the incisions 1200 and one or more active electrode(s) 1004. are positioned adjacent the fatty tissue. Electrically conductive fluid, e.g., isotonic saline, is delivered through tube 1133 and opening 1137 to the tissue. The fluid flows past the return electrode 1012 to the active electrodes 1004 at the distal end of the shaft. The rate of fluid flow is controlled by a valve 417 (Fig. 7) such that the zone between the tissue and electrode support 1002 is constantly immersed in the fluid. The power supply 928 is then turned on and adjusted

such that a high frequency voltage difference is applied between active electrodes 1004 and return electrode 1012. The electrically conductive fluid provides the conduction path between active electrodes 1004 and the return electrode 1012.

In the representative embodiment, the high frequency voltage is sufficient to convert the electrically conductive fluid (not shown) between the target tissue and active electrodes 1004 into an ionized vapor layer or plasma (not shown). As a result of the applied voltage difference between active electrode(s) 1004 and the target tissue (i.e., the voltage gradient across the plasma layer), charged particles in the plasma (e.g., electrons) are accelerated towards the fatty tissue. At sufficiently high voltage differences, these charged particles gain sufficient energy to cause dissociation of the molecular bonds within tissue structures. This molecular dissociation is accompanied by the volumetric removal (i.e., ablative sublimation) of tissue and the production of low molecular weight gases, such as oxygen, nitrogen, carbon dioxide, hydrogen and methane. The short range of the accelerated charged particles within the tissue confines the molecular dissociation process to the surface layer to minimize damage and necrosis to the underlying tissue.

In alternative embodiments, the high frequency voltage is sufficient to heat and soften or separate portions of the fatty tissue from the surrounding tissue. Suction is then applied from a vacuum source (not shown) through lumen 962 to aspirate or draw away the heated fatty tissue. A temperature of about 45°C softens fatty tissue, and a temperature of about 50°C normally liquefies mammalian adipose tissue. This heating and softening of the fatty tissue reduces the collateral damage created when the heated tissue is then removed through aspiration. Alternatively, the present invention may employ a combination of ablation through molecular dissociation, as described above, and heating or softening of the fatty tissue. In this embodiment, some of the fatty tissue is ablated *in situ*, while other portions are softened to facilitate removal through suction.

During the process, the gases will be aspirated through opening 1109 and suction tube 1111 to a vacuum source. In addition, excess electrically conductive fluid, and other fluids (e.g., blood) will be aspirated from the target site to facilitate the surgeon's view. Applicant has also found that tissue fragments are also aspirated through opening 1109 into suction lumen and tube 1111 during the procedure. These tissue fragments are ablated or dissociated with loop electrodes 1040 in a similar mechanism to that described above. That is, as electrically conductive fluid and tissue fragments are aspirated towards loop electrodes 1040, these electrodes 1040 are activated so that a high

frequency voltage is applied between loop electrodes 1040 and return electrode 1012 (of course, the probe may include a different, separate return electrode for this purpose). The voltage is sufficient to vaporize the fluid, and create a plasma layer between loop electrodes 1040 and the tissue fragments so that portions of the tissue fragments are ablated or removed. This reduces the volume of the tissue fragments as they pass through suction lumen to minimize clogging of the lumen.

In one embodiment, loop electrodes 1040 are electrically isolated from the other active electrodes 1004, and electrodes 1040 must be separately activated at the power supply 928. In other embodiments, loop electrodes 1040 will be activated at the same time that active electrodes 1004 are activated. In this case, applicant has found that the plasma layer typically forms when tissue is drawn adjacent to loop electrodes 1040.

Fig. 24 illustrates a cervical liposuction procedure in the face and neck according to the present invention. As shown, the distal portion of the electrosurgical probe 1202 may be inserted in either submental or retroauricular incisions 1204 in the face and neck. In this procedure, the probe 1202 is preferably passed through a portion of the fatty tissue with the power supply 928 activated, but without suction to establish a plane of dissection at the most superficial level of desired fat removal. This plane of dissection allows a smooth, supple, redraping of the region after liposuction has been completed. If this "pretunneling" is not performed in this region, the cannula has a tendency to pull the skin inward, creating small pockets and indentations in the skin, which become evident as superficial irregularities after healing. Pretunneling also enables accurate, safe and proper removal of fat deposits while preserving a fine cushion of subdermal fat.

The present invention may also be used to perform lipectomies in combination with face and neck lifts to facilitate the latter procedures. After the cervical liposuction is complete, the skin flaps are elevated in the temporal, cheek and lateral regions. The lateral neck skin flap dissection is greatly facilitated by the previous suction lipectomy in that region, and the medial and central skin flap elevation may be virtually eliminated.

In another embodiment, the present invention comprises an electrified shaver or microdebrider. Powered instrumentation, such as microdebrider devices and shavers, has been used to remove polyps or other swollen tissue in functional endoscopic sinus surgery and synovial and meniscus tissue and articular cartilage I arthroscopic procedures. These powered instruments are disposable motorized cutters having a rotating



shaft with a serrated distal tip for cutting and resecting tissue. The handle of the microdebrider is typically hollow, and it accommodates a small vacuum, which serves to aspirate debris. In this procedure, the distal tip of the shaft is endoscopically delivered to a target site of the patient's body, and an external motor rotates the shaft and the serrated tip, allowing the tip to cut tissue, which is then aspirated through the instrument.

While microdebriders and shavers of the prior art have shown some promise, these devices suffer from a number of disadvantages. For one thing, these devices sever blood vessels within the tissue, usually causing profuse bleeding that obstructs the surgeon's view of the target site. Controlling this bleeding can be difficult since the vacuuming action tends to promote hemorrhaging from blood vessels disrupted during the procedure. In addition, usually the microdebrider or shaver of the prior art must be periodically removed from the patient to cauterize severed blood vessels, thereby lengthening the procedure. Moreover, the serrated edges and other fine crevices of the microdebrider and shaver can easily become clogged with debris, which requires the surgeon to remove and clean the microdebrider during the surgery, further increasing the length of the procedure.

The present invention solves the above problems by providing one or more active electrodes at the distal tip of the aspiration instrument to effect hemostasis of severed blood vessels at the target site. This minimizes bleeding to clear the surgical site, and to reduce postoperative swelling and pain. In addition, by providing an aspiration electrode on or near the suction lumen, as described above, the present invention avoids the problems of clogging inherent with these devices.

The systems of the present invention may include a bipolar arrangement of electrodes designed to ablate tissue at the target site, and then aspirate tissue fragments, as described above. Alternatively, the instrument may also include a rotating shaft with a cutting tip for cutting tissue in a conventional manner. In this embodiment, the electrode(s) serve to effect hemostasis at the target site and to reduce clogging of the aspiration lumen, while the rotating shaft and cutting tip do the bulk of tissue removal by cutting the tissue in a conventional manner.

The system and method of the present invention may also be useful to efficaciously ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be

advantageous in this application because simply vaporizing and fragmenting cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing necrosis of the underlying tissue.

In another aspect of the invention, systems and methods are provided for treating articular cartilage defects, such as chondral fractures or chondromalacia. The method comprises positioning a distal end of an electrosurgical instrument, such as a probe or a catheter, into close proximity to an articular cartilage surface, either arthroscopically or through an open procedure. High frequency voltage is then applied between an active electrode on the instrument and a return electrode such that electric current flows therebetween and sufficient energy is imparted to the articular cartilage to smooth its surface or to reduce a level of fibrillation in the cartilage. In treating chondromalacia, the voltage between the electrodes is sufficient to heat (e.g., shrink) or ablate (i.e., remove) cartilage strands extending from the articular cartilage surface. In treating chondral fractures, lesions or other defects, the voltage is typically sufficient to ablate or heat at least a portion of the diseased tissue while leaving behind a smooth, contoured surface. In both cases, the method preferably includes forming a substantially continuous matrix layer on the surface of the tissue to seal the tissue, insulating the fracturing and fissuring within the articular cartilage that can cause further degeneration.

The present invention provides a highly controlled application of energy across the articular cartilage, confining the effect to the surface to produce precise and anatomically optimal tissue sculpting that stabilizes the articular cartilage and minimizes collateral tissue injury. Results to date demonstrate that cultures of post-treated chondrocytes within the cartilage tissue remain viable for at least one month, confirming that remaining chondrocytes remain viable after this procedure. Moreover, minimal to no collagen abnormalities have been detected in post-operative cartilage tissue, and diseased areas are smoothed without further evidence of fibrillation. In addition, the bipolar configuration of the present invention controls the flow of current to the immediate region around the distal end of the probe, which minimizes tissue necrosis and the conduction of current through the patient. The residual heat from the electrical energy also provides simultaneous hemostasis of severed blood vessels, which increases visualization of the surgical field for the surgeon, and improves recovery time for the patient. The techniques

of the present invention produce significantly less thermal energy than many conventional techniques, such as lasers and conventional RF devices, which reduces collateral tissue damage and minimizes pain and postoperative scarring. Patients generally experience less pain and swelling, and consequently achieve their range of motion earlier. A more  
5 complete description of exemplary systems and methods for treating articular cartilage can be found in co-pending commonly assigned U.S. Patent Application Nos. 09/183,838, filed October 30, 1998 and 09/177,861, filed October 23, 1998, (Attorney Docket Nos. A-13 and A-2-4, respectively), the complete disclosures of which are incorporated herein by reference.

10 In another aspect, the present invention provides an electrosurgical probe having at least one active loop electrode for resecting and ablating tissue. In comparison to the planar electrodes, ball electrodes, or the like, the active loop electrodes provide a greater current concentration to the tissue at the target site. The greater current concentration can be used to aggressively create a plasma within the electrically  
15 conductive fluid, and hence a more efficient resection of the tissue at the target site. In use, the loop electrode(s) are typically employed to ablate tissue using the Coblation<sup>®</sup> mechanisms as described above. Voltage is applied between the active loop electrodes and a return electrode to volumetrically loosen fragments from the target site through molecular dissociation. Once the tissue fragments are loosened from the target site, the  
20 tissue fragments can be ablated *in situ* within the plasma (i.e., break down the tissue by processes including molecular dissociation or disintegration).

In some embodiments, the loop electrode(s) provide a relatively uniform smooth cutting or ablation effect across the tissue. The loop electrodes generally have a larger surface area exposed to electrically conductive fluid (as compared to the smaller  
25 active electrodes described above), which increases the rate of ablation of tissue.

Applicants have found that the current concentrating effects of the loop electrodes further provide reduced current dissipation into the surrounding tissue, and consequently improved patient comfort through the reduced stimulation of surrounding nerves and muscle. Preferably, the loop electrode(s) extend a sufficient distance from the  
30 electrode support member to achieve current concentration and an improved ablation rate while simultaneously reducing current dissipation into the surrounding medium (which can cause undesirable muscle stimulation, nerve stimulation, or thermal damage to surrounding or underlying tissue). In an exemplary embodiment, the loop electrode has a length from

one end to the other end of about 0.5 mm to 20 mm, usually about 1 mm to 8 mm. The loop electrode usually extends about 0.25 mm to 10 mm from the distal end of the support member, preferably about 1 mm to 4 mm.

The loop electrode(s) may have a variety of cross-sectional shapes.

5 Electrode shapes according to the present invention can include the use of formed wire (e.g., by drawing round wire through a shaping die) to form electrodes with a variety of cross-sectional shapes, such as square, rectangular, L or V shaped, or the like. Electrode edges may also be created by removing a portion of the elongate metal electrode to reshape the cross-section. For example, material can be removed along the length of a solid or  
10 hollow wire electrode to form D or C shaped wires, respectively, with edges facing in the cutting direction. Alternatively, material can be removed at closely spaced intervals along the electrode length to form transverse grooves, slots, threads or the like along the electrodes.

In yet another aspect, the present invention provides an electrosurgical  
15 probe having an aspiration lumen with an opening that is spaced proximally from the active electrodes. Applicants have found that by spacing the suction lumen opening proximal of the active electrodes that a more aggressive plasma can be created. In use, the saline is delivered to the target site and allowed to remain in contact with the electrodes and tissue for a longer period of time. By increasing the distance between the aspiration lumen and  
20 the conductive fluid, the dwell time of the conductive fluid is increased and the plasma can be aggressively created. Advantageously, by moving the aspiration lumen out of the target area, the suction will primarily aspirate blood and gas bubbles from the target site, while leaving the conductive fluid in the target area. Consequently, less conductive fluid and tissue fragments are aspirated from the target site and less clogging of the aspiration lumen  
25 occurs.

In a further aspect, the present invent provides an electrosurgical probe having a conductive fluid delivery lumen that has at least one distal opening positioned at least partially around the active electrodes. The configuration of the openings can be completely around the active electrodes (e.g., O configuration or annular shaped) or  
30 partially around the active electrodes (e.g., U configuration or C configuration) such that delivery of the conductive fluid immerses the active electrodes with conductive fluid during the ablation or resection procedure. Because the conductive fluid can be delivered

from a plurality of directions, the dwell time of the conductive fluid is increased, and consequently the creation of the plasma can be improved.

In a preferred embodiment, the conductive fluid lumen comprises a plurality of openings that are positioned so as to substantially surround the active electrode array.

As above, by "substantially surround", is meant that the openings are at least partially around the active electrodes. In some configurations, the openings will be equally spaced around the active electrodes. However, it will be appreciated that in other alternative embodiments, the openings will only partially surround the active electrodes or can be unevenly spaced about the active electrodes.

With reference to Figs. 32-45 there follows a description of an electrosurgical probe 1400 including a resection unit 1406, according to various embodiments of the instant invention. Probe 1400 is adapted for aggressive ablation, for resection, or for combined ablation and resection of tissue. Probe 1400 may be used in a broad range of surgical procedures including, without limitation, those listed or described hereinabove with reference to the apparatus of Figs. 1-31. In some embodiments, resection unit 1406 may be used to resect tissue by mechanical abrasion, cutting, or severing of tissue. In some embodiments, resection unit 1406 may be used to ablate tissue, e.g., via a Coblation® (cool ablation) mechanism. The Coblation® mechanism has been described hereinabove. Briefly, and without being bound by theory, Coblation® involves the localized generation of a plasma by the application of a high frequency voltage between at least one active electrode and a return electrode in the presence of an electrically conductive fluid. The plasma thus generated causes the breakdown of tissues, e.g., via molecular dissociation, to form low molecular weight ablation by-products. Such low molecular weight ablation by-products may be easily removed from a target site, e.g., via aspiration. Coblation® allows the controlled removal of tissue, in which both the quantity and quality of tissue removed can be accurately determined. In some embodiments, resection unit 1406 may be used for combined resection and ablation: to resect tissue by application of a mechanical force to the tissue and, concurrently therewith, to electrically ablate ("Coblate") the tissue contacted by resection unit 1406. Applicants have found that a combination of mechanical resection and electrical ablation by resection unit 1406 provides advantageous tissue removal, as compared with mechanical resection or electrical ablation alone. Advantages of tissue removal by combined resection and ablation by resection unit 1406 include a more rapid and aggressive tissue removal, as compared with

ablation alone; and a more controlled and less traumatic tissue removal, as compared with mechanical resection alone.

Fig. 32 shows probe 1400 including a shaft 1402 affixed at shaft proximal end portion 1402b to a handle 1404. Resection unit 1406 is disposed on shaft distal end portion 1402a. Although Fig. 32 shows only a single resection unit 1406 on shaft 1402, certain embodiments of the instant invention may include a plurality of resection units 1406 which may be alike or dissimilar in various respects (for example, the size and shape of electrode support 1408, and the number, arrangement, and type of resection electrodes 1410) (Fig. 33). In the embodiment of Fig. 32, a return electrode 1420 is located at shaft distal end portion 1402a. Return electrode 1420 may be in the form of an annular band. Resection unit 1406 is shown in Fig. 32 as being arranged within, or surrounded by, return electrode 1420. In other embodiments, resection unit 1406 may be arranged adjacent to return electrode 1420. Under the invention, shaft 1402 may be provided in a range of different lengths and diameters. Preferably, shaft 1402 has a length in the range of from about 5 cm to about 30 cm; more preferably in the range of from about 10 cm to about 25 cm. Preferably, shaft 1402 has a diameter in the range of from about 1 mm to about 20 mm; more preferably in the range of from about 2 mm to about 10 mm.

Fig. 33 schematically represents resection unit 1406 of probe 1400, wherein resection unit 1406 includes a resection electrode 1410 on a resection electrode support member 1408. In Fig. 33 resection electrode 1410 is represented as a single "box" located within support 1408, however, other arrangements and numbers of resection electrode 1410 are contemplated and are within the scope of the invention (see, for example, Figs. 36A-F, Figs. 41A-C). Resection electrode support 1408 may comprise an electrically insulating, and durable or refractory material, such as a glass, a ceramic, a silicone, a polyurethane, a urethane, a polyimide, silicon nitride, teflon, or alumina, and the like. Resection electrode support 1408 is shown in Fig. 33 as being substantially square in outline, however, a broad range of other shapes are also possible. The size of resection electrode support 1408 may depend on a number of factors, including the diameter or width of shaft 1402. In one embodiment, support 1408 may be mounted laterally on shaft 1402 as an annular band, i.e., support 1408 may completely encircle shaft 1402. Typically support 1408 represents or occupies from about 2% to 100% of the circumference of shaft 1402. More typically, support 1408 occupies from about 50% to 80% of the circumference of shaft 1402, most typically from about 10% to 50% of the circumference

of shaft 1402. In embodiments wherein support 1408 is mounted terminally on shaft 1402, support 1408 typically occupies from about 5% to 100% of the cross-sectional area of shaft 1402, more typically from about 10% to 95% of the cross-sectional area of shaft 1402.

Figs. 34A-D each show an electrosurgical probe 1400, according to certain  
5 embodiments of the invention. Probe 1400 is depicted in Figs. 34A-D as being linear, however, according to various embodiments of the invention, shaft 1402 may include one or more curves or bends therein (see, for example, Fig. 43B). Resection electrodes 1410 are omitted from Figs. 34A-D for the sake of clarity. However, as described elsewhere herein, each resection unit 1406 includes at least one resection electrode 1410 (see, for  
10 example, Figs. 36A-F, 38A-D, 41A-C).

With reference to Fig. 34A, probe 1400 includes a fluid delivery tube 1434, and a fluid delivery port 1430 located distal to resection unit 1406 on shaft distal end portion 1402a. Fluid delivery port 1430 is coupled to fluid delivery tube 1434 via a fluid delivery lumen 1432 (Fig. 35B). Fluid delivery tube 1434 is, in turn, coupled to a source  
15 of an electrically conductive fluid (see, e.g., Fig. 7). Fluid delivery port 1430 is adapted to provide a quantity of an electrically conductive fluid to shaft distal end portion 1402a during a procedure, as is described elsewhere herein in enabling detail.

Fig. 34B shows probe 1400 including an aspiration tube 1444 and an aspiration port 1440 located proximal to resection unit 1406. In the embodiment depicted  
20 in Fig. 34B, aspiration tube 1444 is shown as being connected to probe 1400 at shaft proximal end 1402b, however other arrangements for coupling aspiration tube 1444 to probe 1400 are possible under the invention. Fig. 34C shows probe 1400 including both an aspiration tube 1444 and a fluid delivery tube 1434; and both a fluid delivery port 1430 and an aspiration port 1440. Although fluid delivery port 1430 is depicted in Figs. 34A,  
25 34C as a single port located distal to resection unit 1406, other arrangements of fluid delivery port(s) 1430/1430' with respect to resection unit 1406, are contemplated according to various embodiments of the invention. Aspiration port 1440 is located proximal to resection unit 1406. Preferably, aspiration port 1440 is located a distance of at least 2 mm proximal to resection unit 1406. More preferably, aspiration port 1440 is  
30 located a distance in the range of from about 4 mm to about 50 mm proximal to resection unit 1406. In one embodiment, aspiration port 1440 may have a screen (not shown) to prevent relatively large fragments of resected tissue from entering aspiration lumen 1442 (Fig. 35A). Such a screen may serve as an active electrode and cause ablation of tissue

fragments which contact the screen. Alternatively, the screen may serve as a mechanical sieve or filter to exclude entry of relatively large tissue fragments into lumen 1442.

Fig. 34D shows probe 1400 in which resection unit 1406 is located at the distal terminus of shaft 1402. In this embodiment, return electrode 1420 is located at shaft distal end 1402a, and aspiration port 1440 is located proximal to return electrode 1420. The embodiment of Fig. 34D may further include one or more fluid delivery ports 1430 (see, for example, Figs. 44A-D) for delivering an electrically conductive fluid to, at least, resection unit 1406. In certain embodiments, fluid delivery port(s) 1430 deliver a quantity of an electrically conductive fluid to shaft distal end 1402a sufficient to immerse resection unit 1406 and return electrode 1420. In some embodiments, fluid delivery port(s) 1430 deliver a quantity of an electrically conductive fluid from shaft distal end 1402a sufficient to immerse the tissue at a site targeted for ablation and/or resection.

Fig. 35A shows electrosurgical probe 1400 including resection unit 1406 and aspiration port 1440 proximal to resection unit 1406, according to one embodiment of the invention. Aspiration port 1440 is coupled to aspiration tube 1444 via an aspiration lumen 1442. Aspiration tube 1444 may be coupled to a vacuum source, as is well known in the art. Aspiration lumen 1442 serves as a conduit for removal of unwanted materials (e.g., excess fluids and resected tissue fragments) from the surgical field or target site of an ablation and/or resection procedure, essentially as described hereinabove with reference to other embodiments of an electrosurgical probe. The embodiment of Fig. 35A may further include a fluid delivery device (see, for example, Fig. 35B).

Fig. 35B shows electrosurgical probe 1400 including resection unit 1406 and fluid delivery port 1430 located distal to resection unit 1406, according to one embodiment of the invention. Fluid delivery port 1430 is coupled to fluid delivery tube 1434 via a fluid delivery lumen 1432. Fluid delivery lumen 1432 serves as a conduit for providing a quantity of an electrically conductive fluid to resection unit 1406 and/or the target site of an ablation and resection procedure. The embodiment of Fig. 35B may further include an aspiration device (see, for example, Fig. 35A). In the embodiment of Fig. 35B, tube 1434 is coupled to probe 1400 at handle 1404, however other arrangements for coupling tube 1434 to probe 1400 are also within the scope of the invention.

Figs. 36A-F each show a resection unit 1406a-f as seen in plan view, wherein each resection unit 1406a-f includes a resection electrode support 1408 and at least one resection electrode head 1412, according to various embodiments of the invention.



Each resection electrode 1410 (e.g., Fig. 33), may have a single terminal or resection electrode head 1412, such that each resection electrode head 1412 is independently coupled to a power supply (e.g., power supply 428 of Fig. 7). Alternatively, each resection electrode 1410 may have a plurality of terminals or resection electrode heads 1412. Each resection electrode 1410 may be coupled to a power supply unit (not shown in Figs. 36A-F) via a connection block and connector cable, essentially as described hereinabove (e.g., with reference to Figs. 7 & 10).

Fig. 36A indicates the longitudinal axis 1406' of resection units 1406a-f, as well as electrode support distal end 1408a (indication of longitudinal axis 1406' and support distal end 1408a are omitted from Figs. 36B-F for the sake of clarity, however the orientation of resection units 1406b-f is the same as that of resection unit 1406a). In each of Figs. 36A-F, resection electrode heads 1412 are depicted as having an elongated, substantially rectangular shape in plan view. However, other shapes and arrangements for resection electrode heads 1412 are also within the scope of the invention.

Figs. 36A-F show just some of the arrangements of resection electrode head(s) 1412 on each resection electrode support 1408, according to various embodiments. Briefly, Fig. 36A shows a single resection electrode head 1412 located substantially centrally within support 1408 and aligned approximately perpendicular to longitudinal axis 1406'. Fig. 36B shows a plurality of resection electrode heads 1412 arranged substantially parallel to each other and aligned substantially perpendicular to axis 1406'. Fig. 36C shows a plurality of resection electrode heads 1412 arranged substantially parallel to each other and aligned substantially perpendicular to axis 1406', and an additional resection electrode head 1412 arranged substantially parallel to axis 1406'. Fig. 36D shows a plurality of resection electrode heads 1412 arranged substantially parallel to each other and aligned at an angle intermediate between parallel to axis 1406' and perpendicular to axis 1406'. Fig. 36E shows a plurality of resection electrode heads 1412 including a first substantially parallel array 1412a aligned at a first angle with respect to axis 1406' and a second substantially parallel array 1412b aligned at a second angle with respect to axis 1406'. Fig. 36F shows a plurality of resection electrode heads 1412 having an arrangement similar to that described for Fig. 36E, wherein resection electrode heads 1412 are of different sizes.

Fig. 37 illustrates an angle at which a resection electrode head 1412 may be arranged on electrode support 1408 with respect to the longitudinal axis 1406' of resection

unit 1406. According to certain embodiments, resection electrode heads 1412 may be arranged on electrode support 1408 at an angle in the range of from 0° to about 175° with respect to longitudinal axis 1406'. In embodiments having first and second parallel arrays of resection electrode heads 1412, e.g., Fig. 36E, first array 1412a is preferably arranged at an angle  $\alpha$  in the range of from about 90° to 170°, and more preferably from about 105° to 165°. Second array 1412b is preferably arranged at an angle  $\beta$  in the range of from about 10° to 90°, and more preferably from about 15° to 75°.

Fig. 38A shows in plan view a resection electrode support 1408 arranged on shaft distal end portion 1402a, wherein electrode support 1408 includes resection electrode head 1412. Figs. 38B-D each show a profile of a resection electrode head 1412 on an electrode support 1408 as seen along the line 38B-D of Fig. 38A. From an examination of Figs. 38B-D it can be readily seen that, according to certain embodiments of the invention, resection electrode head 1412 may protrude a significant distance from the external surface of shaft 1402. Typically, each resection electrode head 1412 protrudes from resection electrode support 1408 by a distance in the range of from about 0.1 to 20mm, and preferably by a distance in the range of from about 0.2 to 10mm. Resection electrode head 1412 may have a profile which is substantially square or rectangular; arched or semi-circular; or angular and pointed, as represented by Figs. 38B-D, respectively. Other profiles and shapes for resection electrode head 1412 are also within the scope of the invention. Only one resection electrode head 1412 is depicted per electrode support 1408 in Figs. 38A-D. However, according to the invention, each electrode support 1408 may have a plurality of resection electrode heads 1412 arranged thereon in a variety of arrangements (see, e.g., Figs 36A-F).

In the embodiments of Figs. 38B-D, each electrode head 1412 is in the form of a filament or wire of electrically conductive material. In one embodiment, the filament or wire comprises a metal. Such a metal is preferably a durable, corrosion resistant metal. Suitable metals for construction of resection electrode head 1412 include, without limitation, tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. In embodiments wherein each electrode head 1412 is in the form of a filament or wire, the diameter of the wire is preferably in the range of from about 0.05 mm to about 5 mm, more preferably in the range of from about 0.1 to about 2 mm.

09709035 110300

Figs. 39A-I each show a cross-section of the filament or wire of resection electrode head 1412 as seen, for example, along the lines 39A-I of Fig. 38B. Evidently, a variety of different cross-sectional shapes for resection electrode head 1412 are possible. For example, resection electrode head 1412 may be substantially round or circular, substantially square, or substantially triangular in cross-section, as depicted in Figs. 39A-C, respectively. Resection electrode head 1412 may have a cross-section having at least one curved side. For example, head 1412d of Fig. 39D has two substantially parallel sides and two concave sides. Head 1412e of Fig. 39E has four concave sides forming four cusps, while head 1412f (Fig. 39F) includes three concave sides forming three cusps. Figs. 39G-I each depict a cross-section of a wire or filament having serrations on at least one side thereof. Resection electrode head 1412g comprises a filament having a substantially circular cross-section, wherein the circumference of the filament is serrated. In another embodiment (not shown) a selected portion of the circumference of a substantially round filament may be serrated. Resection electrode head 1412h (Fig. 39H) comprises a filament having a substantially square cross-section, wherein a leading or cutting edge portion 1413h of the filament is serrated. Fig. 39I shows a head 1412i comprising a filament of an electrically conductive material having a substantially crescent-shaped or semi-circular cross-sectional shape, wherein cutting edge portion 1413i is serrated. In addition, other cross-sectional shapes for electrode head 1412 are contemplated and are within the scope of the invention. Preferably, the cross-sectional shape and other features of resection electrode head 1412 promote high current densities in the vicinity of resection electrode head 1412 following application of a high frequency voltage to resection electrode head 1412. More preferably, the cross-sectional shape and other features of resection electrode head 1412 promote high current densities in the vicinity of a leading or cutting edge, e.g., edge 1413h, 1413i, of resection electrode head 1412 following application of a high frequency voltage to resection electrode head 1412. As noted previously, high current densities promote generation of a plasma in the presence of an electrically conductive fluid, and the plasma in turn efficiently ablates tissue via the Coblation<sup>®</sup> procedure or mechanism. Preferably, the cross-sectional shape and other features of resection electrode head 1412 are also adapted for maintenance of the plasma in the presence of a stream of fluid passing over resection electrode head 1412. In one embodiment, the cross-sectional shape and other features of resection electrode head 1412 are also adapted for the efficient

mechanical resection, abrading, or severing of, at least, soft tissue (such as skeletal muscle, skin, cartilage, etc.).

In one embodiment a cutting edge, e.g., edge 1413h, 1413i, is adapted for both ablating and resecting tissue. Depending on the embodiment, cutting edge 1413h, 1413i may be oriented, or point, in various directions relative to the longitudinal axis of shaft 1402. For example, depending on the particular embodiment of probe 1400, and on the particular surgical procedure(s) for which embodiments of probe 1400 are designed to perform, cutting edge 1413h, 1413i may be oriented distally, proximally, or laterally.

Fig. 40 shows a cross-section of a resection electrode head 1412, according to another embodiment of the invention, wherein head 1412 includes a cutting edge 1413, and an insulating layer 1414 disposed on a covered portion of head 1412, and wherein cutting edge 1413 is free from insulating layer 1414. Cutting edge 1413 promotes high current densities in a region between resection electrode head 1412 and the target site upon application of a high frequency voltage to resection electrode head 1412. At the same time, insulating layer 1414 reduces undesirable current flow into tissue or surrounding electrically conducting liquids from covered (insulated) portion of resection electrode head 1412. The application or deposition of insulating layer 1414 to resection electrode head 1412 may be achieved by for example, thin-film deposition of an insulating material using evaporative or sputtering techniques, well known in the art. Insulating layer 1414 provides an electrically insulated non-active portion of resection electrode head 1412, thereby allowing the surgeon to selectively resect and/or ablate tissue, while minimizing necrosis or ablation of surrounding non-target tissue or other body structures.

Fig. 41A illustrates a distal end of an electrosurgical probe showing in plan view resection electrode support 1408 including a plurality of resection electrode heads 1412', according to another embodiment of the invention. In contrast to resection electrode heads 1412 described hereinabove, each resection electrode head 1412' in the embodiment of Figs. 41A-C is in the form of a blade. In one embodiment, each resection electrode head 1412' may have a covered portion having an insulating layer thereon (analogous to insulating layer 1414 of resection electrode head 1412 of Fig. 40). Resection electrode heads 1412' are depicted in Fig. 41A as being arranged in a pair of angled parallel electrode head arrays. However, other arrangements for resection electrode heads 1412' are within the scope of the invention. Fig. 41B shows resection electrode heads 1412' as seen along the lines 41B-41B of Fig. 41A. Each resection electrode head 1412' may

include a cutting edge 1413' adapted for promoting high current density in the vicinity of each resection electrode head 1412' upon application of a high frequency voltage thereto. In one embodiment, cutting edge 1413' is also adapted for severing or mechanical resection of tissue. In one embodiment, cutting edge 1413' is serrated. Cutting edge 1413' is shown in Fig. 41B as facing away from shaft distal end portion 1402a. However, in an analogous situation to that described hereinabove with reference to Figs. 39H-I, various embodiments of probe 1400 may have cutting edge 1413' facing in any direction with respect to the longitudinal axis of shaft 1402, e.g., cutting edge 1413' may face distally, proximally, or laterally. Thus, probe 1400 may be provided in a form suitable for performing a broad range of resection and ablation procedures.

Fig. 41C illustrates shaft distal end 1402a of electrosurgical probe 1400, taken along the lines 41C-41C of Fig. 41A, showing resection electrode heads 1412' on resection electrode support 1408. From an examination of Figs. 41B-C it can be readily appreciated that, according to certain embodiments of the invention, resection electrode heads 1412' may protrude a significant distance from the external surface of shaft 1402. Typically, each resection electrode head 1412' protrudes from resection electrode support 1408 by a distance in the range of from about 0.1 to 20mm, and preferably by a distance in the range of from about 0.2 to 10mm. Each resection electrode head 1412' may comprise a metal blade, wherein the metal blade comprises a metal such as tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys, and the like.

Fig. 42A is a sectional view of shaft 1402 including distal end portion 1402a. Shaft 1402 includes resection unit 1406 and fluid delivery port 1430 for supplying electrically conductive fluid to resection unit 1406 via fluid delivery lumen 1432. A plurality of aspiration ports 1440 are located proximal to resection unit 1406. Aspiration ports 1440 lead to aspiration lumen 1442. Applicants have determined that positioning aspiration ports somewhat distant from resection unit 1406 and delivery port 1430, the dwell time of the electrically conductive fluid is increased, and a plasma can be created more aggressively and consistently. Advantageously, by moving the aspiration ports somewhat distant from the target site, suction will primarily aspirate excess or unwanted fluids (e.g., tissue fluids, blood, etc.) and gaseous ablation by-products from the target site, while the electrically conductive fluid, such as isotonic saline, remains at the target site. Consequently, less conductive fluid and tissue fragments are aspirated from the target

site, and entry of resected tissue fragments into aspiration lumen 1442 is less likely to occur.

In the embodiments of Figs. 42A-B, aspiration lumen 1442 includes at least one digestion electrode 1450. More preferably, aspiration lumen 1442 includes a plurality of digestion electrodes 1450. Each digestion electrode 1450 serves as an active (ablation) electrode and is coupled to a high frequency power supply (e.g. power supply 428 of Fig. 7). Each digestion electrode 1450 is adapted for rapidly breaking down any tissue fragments that may be drawn into aspiration lumen 1442 during a resection and ablation procedure. In this manner, lumen 1442 remains free from blockage, and allows a surgical procedure to be completed conveniently and efficiently without interruption to either unblock lumen 1442 or to replace probe 1400. The shape, arrangement, size, and number, of digestion electrodes 1450 is to some extent a matter of design choice. Preferably, each digestion electrode 1450 is adapted to provide a high current density upon application thereto of a high frequency voltage, thereby promoting rapid and efficient ablation of resected tissue fragments.

In one embodiment, a plurality of digestion electrodes 1450 of a suitable shape and size may be arranged within aspiration lumen 1442 such that digestion electrodes 1450 at least partially overlap or interweave. Such overlapping digestion electrodes 1450 may act, at least to some extent, as a screen to mechanically restrain tissue fragments thereat. While tissue fragments are restrained against one or more digestion electrodes 1450, the latter may efficiently ablate the former to yield low molecular weight ablation by-products which readily pass through lumen 1442 in the aspiration stream. Fig. 42B illustrates in transverse section shaft 1402 taken along the lines 42B-42B of Fig. 42A, and showing fluid delivery lumen 1432 and aspiration lumen 1442, the latter having digestion electrodes 1450 arranged therein. In this embodiment, digestion electrodes 1450 are shown as having pointed surfaces, such as are known to promote high current densities thereat, and digestion electrodes 1450 at least partially interweave with each other.

Figs. 43A-D are side views of shaft distal end portion 1402a of an electrosurgical probe 1400. Fig. 43A shows resection electrode support 1408 disposed laterally on a linear or substantially linear shaft distal end 1402a. Fig. 43B shows resection electrode support 1408 disposed on the terminus of shaft 1402, wherein shaft distal end 1402a includes a bend or curve. In the embodiments of Figs. 43A, 43B, electrode support 1408 protrudes from an external surface of shaft distal end portion 1402a. Typically,

electrode support 1408 protrudes a distance in the range of from about 0 (zero) to about 20 mm from the external surface of shaft 1402. Each resection electrode support 1408 of the invention includes at least one resection electrode terminal or head 1412/1412'. Each resection electrode head 1412/1412' is coupled, e.g. via a connection block and connecting cable, to a high frequency power supply unit, essentially as described hereinabove. However, for the sake of clarity, resection electrode head(s) 1412/1412' are omitted from Figs. 43A-D.

Fig. 43C shows shaft 1402 having resection electrode support 1408 countersunk or recessed within shaft distal end 1402a. In this embodiment, an external surface of resection electrode support 1408 may be aligned, or flush, with an external surface of shaft 1402. In this embodiment, resection electrode heads 1412/1412' (Figs. 38B-D, 41A-C) may protrude from the external surface of shaft distal end 1402a to various extents, as described hereinabove. Fig. 43D shows a shaft distal end portion 1402 having a depression or cavity 1416 therein. In this embodiment, resection electrode support 1408 is housed within cavity 1416. In this embodiment, resection electrode heads 1412/1412' may, or may not, extend above cavity 1416 and from the shaft external surface. In this embodiment the extent, if any, to which resection electrode heads 1412/1412' extend above cavity 1416 is determined by the depth of cavity 1416, as well as by the height of resection electrode support 1408, and the height of resection electrode heads 1412/1412'. The embodiment of Fig. 43D serves to isolate non-target tissue from resection electrode heads 1412/1412', thereby minimizing collateral damage to such tissue during a resection and ablation procedure.

Referring now to Figs. 44A-D, a fluid delivery device for delivering an electrically conductive fluid to resection unit 1406 or to tissue at a target site can include a single fluid delivery port 1430 (e.g., Fig. 34A) or a plurality of ports 1430. In exemplary embodiments of probe 1400, ports 1430 are disposed around a perimeter of resection unit 1406, and are positioned to deliver the conductive fluid to resection electrode head(s) 1412/1412'. As shown in Fig. 44A, a plurality of ports 1430 may be arranged around a distal portion of resection unit 1406. In the embodiment of Fig. 44B a plurality of ports 1430 are arranged around the entire perimeter of resection unit 1406. The arrows shown in Fig. 44B indicate a direction in which an electrically conductive fluid may be delivered from the plurality of fluid delivery ports 1430. In one embodiment, fluid delivery ports 1430 are rounded or substantially circular in outline.

As shown in Fig. 44C, a fluid delivery port 1430' may be in the form of an elongated opening or slit extending around a distal portion of resection unit 1406. In the embodiment of Fig. 44D port 1430' is in the form of a single slit extending around the perimeter of resection unit 1406. In each embodiment (Figs. 44A-D), delivery ports

5 1430/1430' preferably deliver electrically conductive fluid in the direction of resection unit 1406. The amount of electrically conductive fluid delivered to resection unit 1406, and the timing or periodicity of such fluid delivery, may be controlled by an operator (surgeon). In one embodiment, the amount of electrically conductive fluid delivered to resection unit 1406 is sufficient to, at least transiently, immerse resection electrode heads 1412/1412' in

10 the electrically conductive fluid.

Fig. 45 shows a shaft distal end portion 1402a of shaft 1402, according to one embodiment of the invention. In this embodiment, resection unit 1406/resection electrode support 1408 is disposed on return electrode 1420, wherein return electrode 1420 comprises an exposed region of shaft 1402. By "exposed region" is meant a region of

15 shaft distal end portion 1402a which is not covered by an insulating sleeve or sheath 1460. Insulating sleeve 1460 may comprise a layer or coating of a flexible insulating material, such as various plastics (e.g., a polyimide or polytetrafluoroethylene, and the like) as is well known in the art. In this embodiment, a plurality of fluid delivery ports 1430 are positioned within return electrode 1420 such that when the electrically conductive fluid

20 contacts resection electrode heads 1412/1412' on resection electrode support 1408, an electrical circuit, or current flow path, is completed. A plurality of aspiration ports 1440 are spaced proximally from resection electrode support 1408 for removing unwanted fluids, such as ablation by-products, from the vicinity of resection unit 1406. Resection electrode support 1408 may be substantially square, rectangular, oval, circular, etc.

25 Typically, resection electrode support 1408 has a dimension in the longitudinal direction of the shaft (i.e., a length) in the range of from about 1 mm to about 20mm, more typically in the range of from about 2 mm to about 10mm.

Referring now to Fig. 46, a surgical kit 1500 for resecting and/or ablating tissue according to the invention will now be described. Fig. 46 schematically represents

30 surgical kit 1500 including electrosurgical probe 1400, a package 1502 for housing probe 1400, a surgical instrument 1504, and an instructions for use 1506. Instructions for use 1506 include instructions for using probe 1400 in conjunction with apparatus ancillary to probe 1400, such as power supply 428 (Fig. 7). Package 1502 may comprise any suitable



package, such as a box, carton, etc. In an exemplary embodiment, package 1502 includes a sterile wrap or wrapping 1504 for maintaining probe 1400 under aseptic conditions prior to performing a surgical procedure.

An electrosurgical probe 1400 of kit 1500 may comprise any of the  
5 embodiments described hereinabove. For example, probe 1400 of kit 1500 may include shaft 1402 having at least one resection electrode 1410 at shaft distal end 1402a, and at least one connector (not shown) extending from the at least one resection electrode 1410 to shaft proximal end 1402b for coupling resection electrode 1410 to a power supply. Probe 1400 and kit 1500 are disposable after a single procedure. Probe 1400 may or may not  
10 include a return electrode 1420.

Instructions for use 1506 generally includes, without limitation, instructions for performing the steps of: adjusting a voltage level of a high frequency power supply to effect resection and/or ablation of tissue at the target site; connecting probe 1400 to the high frequency power supply; positioning shaft distal end 1402a within an electrically  
15 conductive fluid at or near the tissue at the target site; and activating the power supply to effect resection and/or ablation of the tissue at the target site. An appropriate voltage level of the power supply is usually in the range of from about 40 to 400 volts rms for operating frequencies of about 100 to 200 kHz. Instructions 1506 may further include instruction for advancing shaft 1402 towards the tissue at the target site, and for moving shaft distal end  
20 portion 1402a in relation to the tissue. Such movement may be performed with or without the exertion of a certain mechanical force on the target tissue via resection unit 1406, depending on parameters such as the nature of the procedure to be performed, the type of tissue at the target site, the rate at which the tissue is to be removed, and the particular design or embodiment of probe 1400/resection unit 1406.

Figs. 47A-B schematically represent a method of performing a resection and  
25 ablation electrosurgical procedure, according to another embodiment of the invention, wherein step 1600 (Fig. 47A) involves providing an electrosurgical probe having a resection unit. The probe provided in step 1600 includes a shaft distal end, wherein the resection unit is disposed at the shaft distal end, either laterally or terminally. The  
30 resection unit includes an electrode support comprising an insulating material and at least one resection electrode head arranged on the electrode support. Step 1602 involves adjusting a voltage level of a power supply, wherein the power supply is capable of providing a high frequency voltage of a selected voltage level and frequency. The voltage

selected is typically between about 5 kHz and 20 MHz, essentially as described hereinabove. The RMS voltage will usually be in the range of from about 5 volts to 1000 volts, and the peak-to-peak voltage will be in the range of from about 10 to 2000 volts, again as described hereinabove. The actual or preferred voltage will depend on a number of factors, including the number and size of resection electrodes comprising the resection unit.

Step 1604 involves coupling the probe to the power supply unit. Step 1606 involves advancing the resection unit towards tissue at a target site whence tissue is to be removed. In optional step 1608, a quantity of an electrically conductive fluid may be applied to the resection unit and/or to the target site. For performance of a resection and ablation procedure in a dry field, optional step 1608 is typically included in the procedure.

Step 1608 may involve the application of a quantity of an electrically conductive fluid, such as isotonic saline, to the target site. The quantity of an electrically conductive fluid may be controlled by the operator of the probe. The quantity of an electrically conductive fluid applied in step 1608 may be sufficient to completely immerse the resection unit and/or to completely immerse the tissue at the target site. Step 1610 involves applying a high frequency voltage to the resection unit via the power supply unit. Step 1612 involves contacting the tissue at the target site with the resection unit.

With reference to Fig. 47B, optional step 1614 involves exerting pressure on the tissue at the target site by applying a force to the probe, while the resection unit is in contact with the tissue at the target site, in order to effect resection of tissue. Typically, such a force is applied manually by the operator (surgeon), although mechanical application of a force to the probe, e.g., by a robotic arm under computer control, is also possible. The amount of any force applied in optional step 1614 will depend on factors such as the mode of operation of the probe, the nature of the tissue to be removed, the design or embodiment of the probe, and the amount of tissue to be resected. By "mode of operation of the probe" is meant whether the probe is used solely or primarily as an ablation probe, or primarily as a resecting probe. For example, in the absence of any mechanical force applied to the tissue, tissue removal from the target site is primarily or solely by ablation. On the other hand, with the electrical power turned off, either transiently or for all or a portion of a procedure, the probe may be used for mechanical resection of tissue. Typically, however, the probe is used for the concurrent electrical ablation and mechanical resection of tissue.

Step 1616 involves moving the resection unit of the probe with respect to the tissue at the target site. Typically, step 1616 involves moving the resection unit and the at least one resection electrode head in a direction substantially perpendicular to a direction of any pressure exerted in step 1614, or in a direction substantially parallel to a surface of the tissue at the target site. Typically, step 1616 is performed concurrently with one or more of steps 1608 through 1614. In one embodiment, step 1616 involves repeatedly moving the resection unit with respect to the tissue at the target site until an appropriate quantity of tissue has been removed from the target site. Typically, a portion of the tissue removed from the target site is in the form of resected tissue fragments. Step 1618 involves aspirating the resected tissue fragments from the target site via at least one aspiration port on the shaft, wherein the at least one aspiration port is coupled to an aspiration lumen. In one embodiment, the probe includes at least one digestion electrode capable of aggressively ablating resected tissue fragments. Step 1620 involves ablating resected tissue fragments with the at least one digestion electrode. In one embodiment, the at least one digestion electrode is arranged within the aspiration lumen, and the resected tissue fragments are ablated within the aspiration lumen.

Fig. 48 schematically represents a method of making a resection and ablation electrosurgical probe, according to the invention, wherein step 1700 involves providing a shaft having a resection unit. The shaft provided in step 1700 includes a shaft proximal end and a shaft distal end, wherein the resection unit is disposed at the shaft distal end, either laterally or terminally. In one embodiment, the shaft comprises an electrically conductive lightweight metal cylinder. The resection unit includes an electrode support comprising an insulating material and at least one resection electrode arranged on the electrode support. Each resection electrode includes a resection electrode head. Each resection electrode head typically comprises a wire, filament, or blade of a hard or rigid, electrically conductive solid material, such as tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys, and the like.

Typically, the shaft provided in step 1700 further includes at least one digestion electrode capable of aggressively ablating tissue fragments. In one embodiment, the at least one digestion electrode is arranged within the aspiration lumen. Each digestion electrode typically comprises an electrically conductive metal, such as tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and

nickel or its alloys, aluminum, gold, or copper, and the like. Typically, the shaft provided in step 1700 further includes a return electrode.

In one embodiment, the method includes step 1702 which involves encasing a portion of the shaft within an insulating sleeve to provide an electrically insulated proximal portion of the shaft and an exposed distal portion of the shaft. The exposed distal portion of the shaft defines a return electrode of the probe. The insulating sleeve typically comprises a substantially cylindrical length of a flexible insulating material such as polytetrafluoroethylene, a polyimide, and the like. Such flexible insulating materials are well known in the art. In one embodiment, the resection electrode support is disposed on the return electrode. The resection electrode support typically comprises an electrically insulating material such as a glass, a ceramic, a silicone, a polyurethane, a urethane, a polyimide, silicon nitride, teflon, alumina, or the like. The electrode support serves to electrically insulate the at least one resection electrode head from the return electrode. Step 1704 involves providing a handle having a connection block. Step 1706 involves coupling the resection electrodes and the digestion electrodes to the connection block. The connection block provides a convenient mechanism by which the resection and digestion electrodes may be coupled to a high frequency power supply. Step 1708 involves affixing the shaft proximal end to the handle.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, it should be noted that the invention is not limited to an electrode array comprising a plurality of active electrodes. The invention could utilize a plurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single active electrode may be sufficient to contract collagen tissue, ablate tissue, or the like.

In addition, the active and return electrodes may both be located on a distal tissue treatment surface adjacent to each other. The active and return electrodes may be located in active/return electrode pairs, or one or more return electrodes may be located on the distal tip together with a plurality of electrically isolated active electrodes. The proximal return electrode may or may not be employed in these embodiments. For example, if it is desired to maintain the current flux lines around the distal tip of the probe, the proximal return electrode will not be desired.

In regards to the electrosurgical probes having a fluid delivery lumen, the electrosurgical probe can include a ring return electrode that is positioned proximal of the active electrodes and the openings of the fluid delivery lumen can be disposed on the distal end of the shaft. In yet other alternative embodiments, the fluid delivery opening can be  
5 positioned in the electrode support member such that the electrically conductive fluid will be delivered directly to the active electrodes.

While the exemplary embodiments of the present invention have been described in detail, by way of example and for clarity of understanding, a variety of changes, adaptations, and modifications will be obvious to those of skill in the art.  
10 Therefore, the scope of the present invention is limited solely by the appended claims.

## WHAT IS CLAIMED IS:

1. An electrosurgical apparatus for resecting and ablating tissue at a target site, comprising:

5 a shaft having a shaft distal end portion and a shaft proximal end portion;  
and

a resection unit located at the shaft distal end portion, the resection unit including a resection electrode support and at least one resection electrode arranged on the resection electrode support, wherein the at least one resection electrode is capable of  
10 mechanically severing the tissue at the target site and the at least one resection electrode is further capable of generating a plasma from an electrically conductive fluid and ablating the tissue via a cool ablation mechanism, wherein the tissue at the target site is exposed to a temperature not exceeding 90° C.

15 2. The electrosurgical apparatus of claim 1, wherein each of the at least one resection electrodes comprises a resection electrode head.

3. The electrosurgical apparatus of claim 2, wherein the resection electrode support protrudes from an external surface of the shaft.

20 4. The electrosurgical apparatus of claim 1, wherein the resection electrode support is arranged laterally or terminally on the shaft distal end portion.

25 5. The electrosurgical apparatus of claim 1, wherein an arrangement of the resection electrode support on the shaft distal end portion is selected from the group consisting of protruding from a shaft external surface and recessed within the shaft external surface.

30 6. The electrosurgical apparatus of claim 1, wherein the shaft distal end portion includes a cavity, and the resection electrode support is arranged in the cavity.

7. The electrosurgical apparatus of claim 1, wherein the shaft distal end portion includes a curve.

8. The electrosurgical apparatus of claim 2, wherein the resection electrode head protrudes from an external surface of the shaft by a distance in the range of from about 0.1 to about 20 mm.

9. The electrosurgical apparatus of claim 2, wherein the resection electrode head comprises a wire or a blade.

10. The electrosurgical apparatus of claim 2, wherein the resection electrode head comprises a wire having a cross-sectional shape selected from the group consisting of substantially round, substantially square, and substantially triangular.

11. The electrosurgical apparatus of claim 2, wherein the resection electrode head comprises a wire having a cross-sectional shape including at least one cusp.

12. The electrosurgical apparatus of claim 2, wherein the resection electrode head comprises a serrated wire.

13. The electrosurgical apparatus of claim 2, wherein the resection electrode head comprises a wire having a cutting edge.

14. The electrosurgical apparatus of claim 13, wherein the cutting edge is serrated.

15. The electrosurgical apparatus of claim 13, wherein the resection electrode head comprises a wire having an insulating layer disposed on a covered portion of the wire, wherein the covered portion of the wire excludes the cutting edge.

16. The electrosurgical apparatus of claim 2, wherein the resection electrode head comprises a material selected from the group consisting of: tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys.

17. The electrosurgical apparatus of claim 1, wherein the resection unit includes a plurality of resection electrode heads.

18. The electrosurgical apparatus of claim 17, wherein the plurality of resection electrode heads are capable of mechanically resecting tissue to provide a plurality of resected tissue fragments, and the plurality of resection electrode heads are further capable of electrically ablating the resected tissue fragments.

19. The electrosurgical apparatus of claim 17, wherein the plurality of resection electrode heads comprise at least one resection electrode array.

20. The electrosurgical apparatus of claim 19, wherein the at least one resection electrode array comprises a plurality of resection electrode heads arranged substantially parallel to each other.

21. The electrosurgical apparatus of claim 17, wherein the plurality of resection electrode heads comprise a first resection electrode head array and a second resection electrode head array, wherein the first resection electrode head array is arranged at an angle to the longitudinal axis of the resection unit in the range of from about 105° to about 165°, and the second resection electrode head array is arranged at an angle to the longitudinal axis of the resection unit in the range of from about 15° to about 75°.

22. The electrosurgical apparatus of claim 2, further comprising a return electrode, wherein the at least one resection electrode head is coupled to a high frequency power supply for applying a high frequency voltage to the at least one resection electrode head, and the at least one resection electrode head is adapted to provide a high current density in the vicinity of the at least one resection electrode head upon application of a high frequency voltage between the at least one resection electrode head and the return electrode.

23. The electrosurgical apparatus of claim 22, wherein the high frequency voltage is characterized as having a peak-to-peak voltage in the range of from



about 10 to 2000 volts, a RMS voltage in the range of from about 5 to 1000 volts, and a frequency in the range of from about 5 KHz to 20 MHz.

24. The electrosurgical apparatus of claim 2, further comprising a return  
5 electrode, wherein the resection electrode head is adapted to promote generation of a  
plasma in the vicinity of the resection electrode head upon application of a high frequency  
voltage between the at least one resection electrode and the return electrode, and the  
plasma causes molecular dissociation of high molecular weight tissue components to yield  
low molecular weight ablation by-products.

25. The electrosurgical apparatus of claim 1, wherein the resection  
10 electrode support is disposed on a return electrode, and the resection electrode support  
electrically insulates the at least one resection electrode from the return electrode.

26. The electrosurgical apparatus of claim 1, further comprising at least  
15 one digestion electrode, wherein the at least one digestion electrode is coupled to a high  
frequency power supply, and the at least one digestion electrode is capable of aggressive  
ablation of tissue fragments.

27. The electrosurgical apparatus of claim 1, further comprising at least  
20 one fluid delivery port for delivering an electrically conductive fluid to the resection unit  
or to the target site.

28. The electrosurgical apparatus of claim 27, wherein the at least one  
25 fluid delivery port comprises a slit at least partially surrounding the resection unit.

29. The electrosurgical apparatus of claim 27, wherein the at least one  
fluid delivery port comprises a plurality of fluid delivery ports at least partially  
surrounding the resection unit.

30. The electrosurgical apparatus of claim 27, wherein the at least one  
30 fluid delivery port completely surrounds the resection electrode support.

31. The electrosurgical apparatus of claim 27, wherein the at least one fluid delivery port is located within a return electrode.

32. The electrosurgical apparatus of claim 1, further comprising at least one aspiration port coupled to an aspiration lumen, the aspiration lumen disposed within the shaft.

33. The electrosurgical apparatus of claim 32, wherein the at least one aspiration port is located on an external surface of the shaft at a distance of from about 5mm to about 50 mm proximal to the resection electrode support.

34. The electrosurgical apparatus of claim 32, further comprising at least one digestion electrode arranged within the aspiration lumen, the at least one digestion electrode coupled to a high frequency power supply for supplying a high frequency voltage to the at least one digestion electrode, the aspiration lumen serving as a conduit for removal of excess fluids and resected tissue fragments from the target site, and the at least one digestion electrode capable of breaking down the resected tissue fragments within the aspiration lumen to yield low molecular weight ablation by-products, wherein the resected tissue fragments are removed from the target site.

35. The electrosurgical apparatus of claim 26, wherein the at least one digestion electrode comprises a plurality of digestion electrodes.

36. The electrosurgical apparatus of claim 35, wherein the plurality of digestion electrodes at least partially interweave with each other.

37. The electrosurgical apparatus of claim 27, wherein the at least one fluid delivery port delivers an electrically conductive fluid in a plurality of directions such that the electrically conductive fluid immerses the at least one resection electrode.

38. The electrosurgical apparatus of claim 1, wherein the at least one resection electrode is coupled to a high frequency power supply for delivering a high frequency voltage between the at least one resection electrode and a return electrode,

wherein the high frequency voltage is sufficient to ablate at least a portion of the tissue at the target site, and the tissue ablated at the target site is exposed to a temperature in the range of from about 45° to 90° C.

5                   39.     The electrosurgical apparatus of claim 1, wherein the resection electrode support electrically insulates the at least one resection electrode from the return electrode.

10                   40.     The electrosurgical apparatus of claim 1, wherein the resection electrode support member comprises a material selected from the group consisting of a glass, a ceramic, a silicone, a urethane, a polyurethane, a polyimide, silicon nitride, teflon, and alumina.

15                   41.     An electrosurgical instrument for resecting and ablating tissue at a target site, comprising:

                  a shaft having a shaft distal end portion and a shaft proximal end portion;

                  a resection unit located at the shaft distal end portion, the resection unit including a resection electrode support and a plurality of resection electrode heads arranged on the resection electrode support;

20                   an aspiration device including at least one aspiration port proximal to the resection unit and an aspiration lumen coupled to the at least one aspiration port; and  
                  at least one digestion electrode arranged on the aspiration device.

25                   42.     The electrosurgical instrument of claim 41, wherein each of the plurality of resection electrode heads comprises a wire loop or a blade.

30                   43.     The electrosurgical instrument of claim 41, wherein the aspiration device accommodates an aspiration stream including excess fluids and resected tissue fragments, the at least one digestion electrode arranged within the aspiration lumen and coupled to a high frequency power supply, and the at least one digestion electrode adapted for aggressive ablation of the resected tissue fragments.

44. The electrosurgical instrument of claim 41, further comprising an electrically insulating sleeve covering the shaft to a position proximal of the resection unit.

45. The electrosurgical instrument of claim 41, further comprising a fluid delivery lumen leading to at least one fluid delivery port disposed adjacent to the resection electrode support.

46. The electrosurgical instrument of claim 45, further comprising a return electrode disposed on the shaft distal end portion, wherein the at least one fluid delivery port delivers an electrically conductive fluid to provide a current flow path between the return electrode and the plurality of resection electrode heads.

47. The electrosurgical instrument of claim 46, wherein each of the at least one fluid delivery port delivers the electrically conductive fluid towards the plurality of resection electrode heads, and the plurality of resection electrode heads generate a plasma from the electrically conductive fluid upon application of a high frequency voltage to the plurality of resection electrode heads, and the plasma causes molecular dissociation of the tissue at a temperature in the range of from about 45° to 90° C.

48. The electrosurgical instrument of claim 41, wherein each of the plurality of resection electrode heads includes a surface geometry configured to promote substantially high electric field intensities in the vicinity of the plurality of resection electrode heads when a high frequency voltage is applied to the plurality of resection electrode heads, wherein the high frequency voltage is characterized by a peak-to-peak voltage in the range of from about 10 to 2000 volts, a RMS voltage in the range of from about 5 to 1000 volts, and a frequency in the range of from about 5 KHz to 20 MHz, and the electric field intensities are sufficient to vaporize an electrically conductive fluid in contact with the plurality of resection electrode heads.

49. The electrosurgical instrument of claim 41, further comprising a return electrode, the resection electrode support disposed on the return electrode.

50. The electrosurgical instrument of claim 49, wherein the plurality of

resection electrode heads and the return electrode are configured such that, upon the application of a suitable high frequency voltage therebetween, an electrically conductive fluid is vaporized in a thin vapor layer over at least a portion of the resection unit and energy is discharged from the vapor layer resulting in molecular dissociation of tissue at the target site.

51. A method of removing tissue at a target site of a patient, comprising:

a) advancing a shaft distal end portion of an electrosurgical probe towards the target site, the shaft distal end portion having a resection unit disposed thereon, the resection unit including at least one resection electrode head adapted for mechanically severing body tissue components and the at least one resection electrode head further adapted for effecting molecular dissociation of body tissue components to form low molecular weight ablation by-products, wherein the body tissue components are exposed to a temperature not exceeding 90° C ; and

b) applying a high frequency voltage between the at least one resection electrode head and a return electrode.

52. The method of claim 51, further comprising:

c) contacting the tissue at the target site with the at least one resection electrode head, such that the tissue at the target site is removed by at least one mechanism selected from the group consisting of mechanical resection and molecular dissociation.

53. The method of claim 52, further comprising:

d) concurrently with said step c), exerting a mechanical force on the at least one resection electrode head such that pressure is exerted by the at least one resection electrode head on the tissue at the target site, wherein the mechanical force exerted results in resection of at least a portion of the tissue at the target site to form resected tissue fragments.

54. The method of claim 53, wherein at least a portion of the resected tissue fragments undergo molecular dissociation as a result of said step b) to yield low molecular weight ablation by-products.

55. The method of claim 53, further comprising:

e) during said steps b), c), and d), moving the at least one resection electrode head with respect to the tissue at the target site.

56. The method of claim 53, wherein the shaft further includes an aspiration lumen having at least one digestion electrode disposed therein, and the method further comprises:

f) aspirating the resected tissue fragments into the aspiration lumen; and  
g) applying a high frequency voltage to the at least one digestion electrode

such that components of the resected tissue fragments undergo molecular dissociation within the aspiration lumen.

57. The method of claim 55, wherein said step e) comprises moving the at least one resection electrode head in a direction substantially perpendicular to a direction of the mechanical force exerted.

58. The method of claim 55, wherein said step e) comprises moving the at least one resection electrode head in a direction substantially parallel to a surface of the tissue at the target site.

59. The method of claim 55, further comprising:

h) successively repeating said step e) until an appropriate volume of tissue has been removed from the target site.

60. The method of claim 51, further comprising:

i) delivering an electrically conductive fluid to the target site.

61. The method of claim 51, wherein the target site is aspirated by a vacuum source coupled to at least one aspiration port, wherein the at least one aspiration port is located a distance of from about 5mm to about 50 mm proximal to the resection unit.

62. The method of claim 51, wherein the at least one resection electrode head comprises a plurality of resection electrode heads arranged on the resection unit as a resection electrode head array.

5 63. The method of claim 51, wherein the at least one resection electrode head is coupled to a power supply, the power supply applies a high frequency voltage to the at least one resection electrode head, the at least one resection electrode head promotes a high current density thereat in response to the applied high frequency voltage, the at least one resection electrode head is in contact with an electrically conductive fluid, and  
10 application of the high frequency voltage generates a plasma from the electrically conductive fluid.

64. The method of claim 63, wherein the plasma causes molecular dissociation of tissue components at the target site, and the molecular dissociation of the  
15 tissue components results in ablation of the tissue at the target site.

65. The method of claim 60, wherein said step i) comprises delivering the electrically conductive fluid via at least one fluid delivery port.

20 66. The method of claim 65, wherein the at least one fluid delivery port comprises at least one slit, the at least one slit at least partially surrounding the resection unit.

25 67. The method of claim 65, wherein the at least one fluid delivery port comprises a plurality of fluid delivery ports at least partially surrounding the resection unit.

68. The method of claim 60, wherein said step i) comprises immersing the at least one resection electrode head in the electrically conductive fluid.

30 69. The method of claim 51, wherein said step b) comprises applying sufficient voltage to the at least one resection electrode in the presence of an electrically





09709035 110800

a) providing a shaft including a shaft distal end and a shaft proximal end, the shaft distal end having at least one resection unit thereon, the at least one resection unit including a resection electrode support and at least one resection electrode head, wherein the at least one resection electrode head is adapted for mechanical resection of tissue and for effecting molecular dissociation of tissue components via a cool ablation procedure at a temperature not exceeding 90° C;

b) providing a handle; and

c) affixing the handle to the shaft.

76. The method of claim 75, wherein said step a) comprises providing a shaft having at least one aspiration port coupled to an aspiration lumen, wherein the at least one aspiration port is located proximal to the at least one resection unit, and the aspiration lumen is disposed within the shaft.

77. The method of claim 76, wherein said step a) comprises providing a shaft having at least one digestion electrode adapted for digesting resected tissue fragments suspended in an electrically conductive fluid, wherein the at least one digestion electrode is disposed within the aspiration lumen.

78. The method of claim 77, wherein said step b) comprises providing a handle having a connection block, the at least one digestion electrode and the at least one resection electrode head are coupled to the connection block, and the connection block is adapted for coupling the at least one digestion electrode and the at least one resection electrode head to a high frequency power supply.

79. The method of claim 76, wherein the shaft includes a plurality of digestion electrodes arranged within the aspiration lumen.

80. The method of claim 75, further comprising the step of:

d) encasing a proximal portion of the shaft within an insulating sleeve to provide a distal exposed portion of the shaft, wherein the distal exposed portion of the shaft defines a return electrode.

81. The method of claim 80, wherein said step a) comprises providing a shaft having the at least one resection unit disposed on the return electrode.

82. The method of claim 75, wherein said step a) comprises providing a shaft having at least one fluid delivery port coupled to a fluid delivery lumen, wherein the at least one fluid delivery port at least partially surrounds the at least one resection unit.

83. The method of claim 75, wherein said step a) comprises providing a shaft wherein the at least one resection unit includes a resection electrode support and the at least one resection electrode head comprises a plurality of resection electrode heads arranged on the resection electrode support, wherein each of the plurality of resection electrode heads comprises a wire or a blade.

84. The method of claim 75, wherein the shaft includes at least one digestion electrode, and the handle includes a connection block for coupling the probe to a high frequency power supply, and the method further comprises:

- e) coupling the at least one resection electrode to the connection block; and
- f) coupling the at least one digestion electrode to the connection block.

85. The method of claim 75, wherein the at least one resection electrode head includes a cutting edge and a covered portion, the covered portion having an insulating layer disposed thereon.

# SYSTEMS AND METHODS FOR ELECTROSURGICAL ABLATION AND RESECTION

## ABSTRACT OF THE DISCLOSURE

5

Methods and apparatus for resecting and ablating tissue at a target site of a patient, the apparatus including a probe having an elongate shaft. The shaft includes a shaft distal end portion and a shaft proximal end portion, and a resection unit located at the shaft distal end portion. The resection unit includes a resection electrode support and at least one resection electrode arranged on the resection electrode support. The at least one resection electrode includes a resection electrode head. The probe and resection electrode head are adapted for concurrent electrical ablation and mechanical resection of target tissue. The shaft may include at least one digestion electrode capable of aggressively ablating resected tissue fragments. At least one fluid delivery port on the shaft distal end portion may provide an electrically conductive fluid to the resection unit or to the target site. The shaft may include at least one aspiration port, located proximal to the resection unit, for aspirating excess or unwanted fluids and resected tissue fragments from the target site. The at least one aspiration port is coupled to an aspiration lumen. The at least one digestion electrode may be arranged within the aspiration lumen for ablation of tissue fragments therein. In use, the digestion and resection electrodes of the probe are coupled to a high frequency power supply. A surgical kit comprising the probe is also disclosed, together with a method of making the probe.

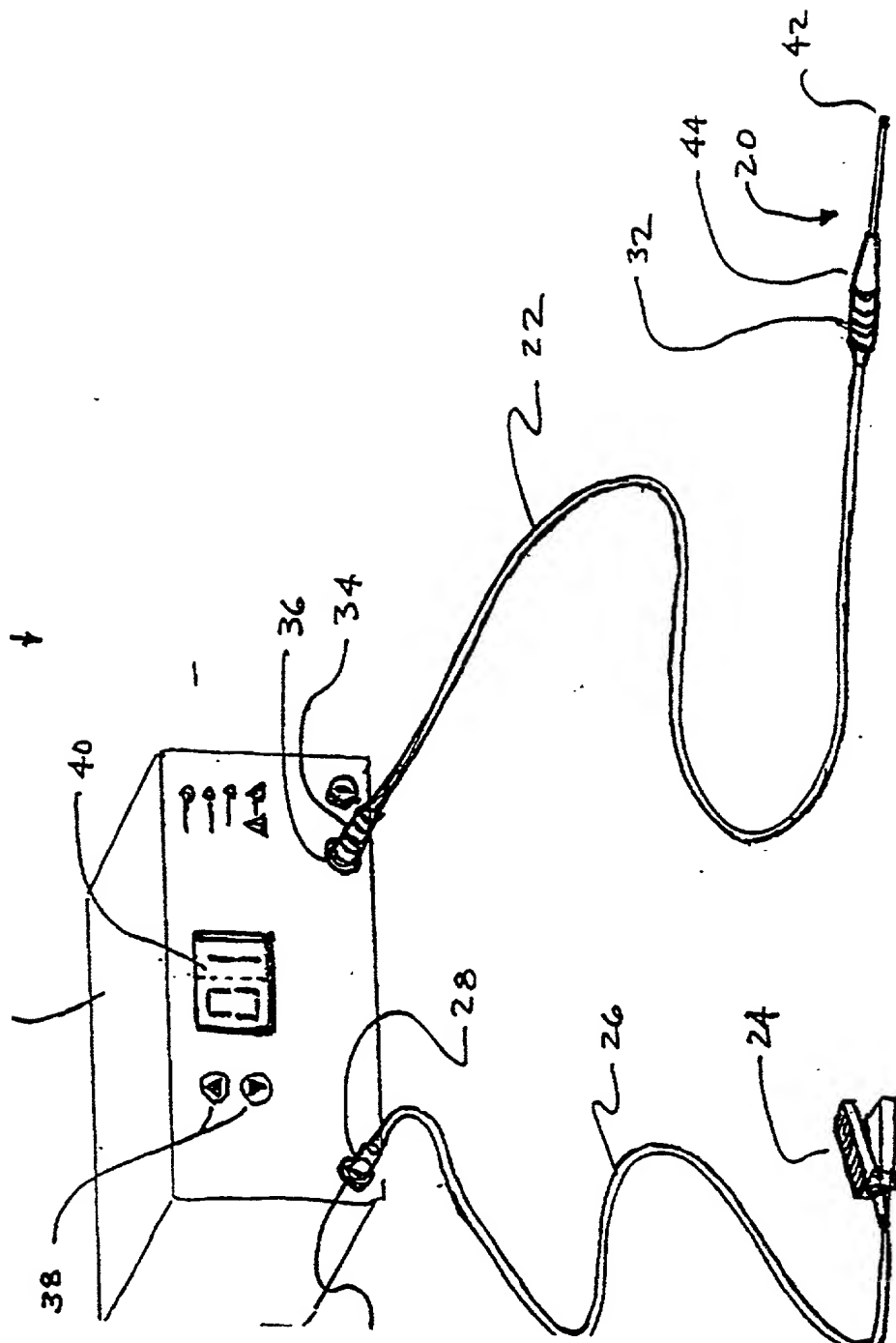
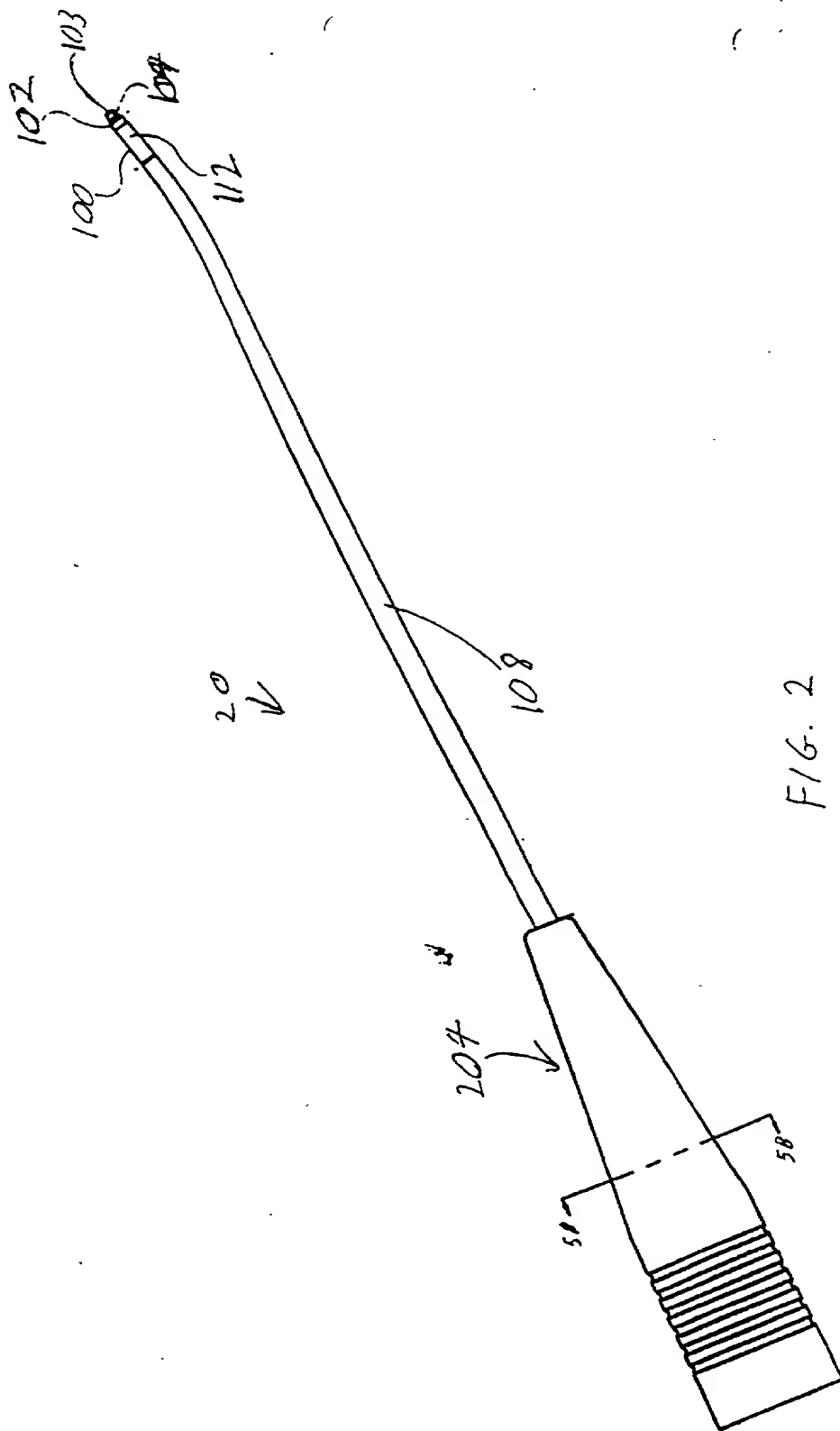
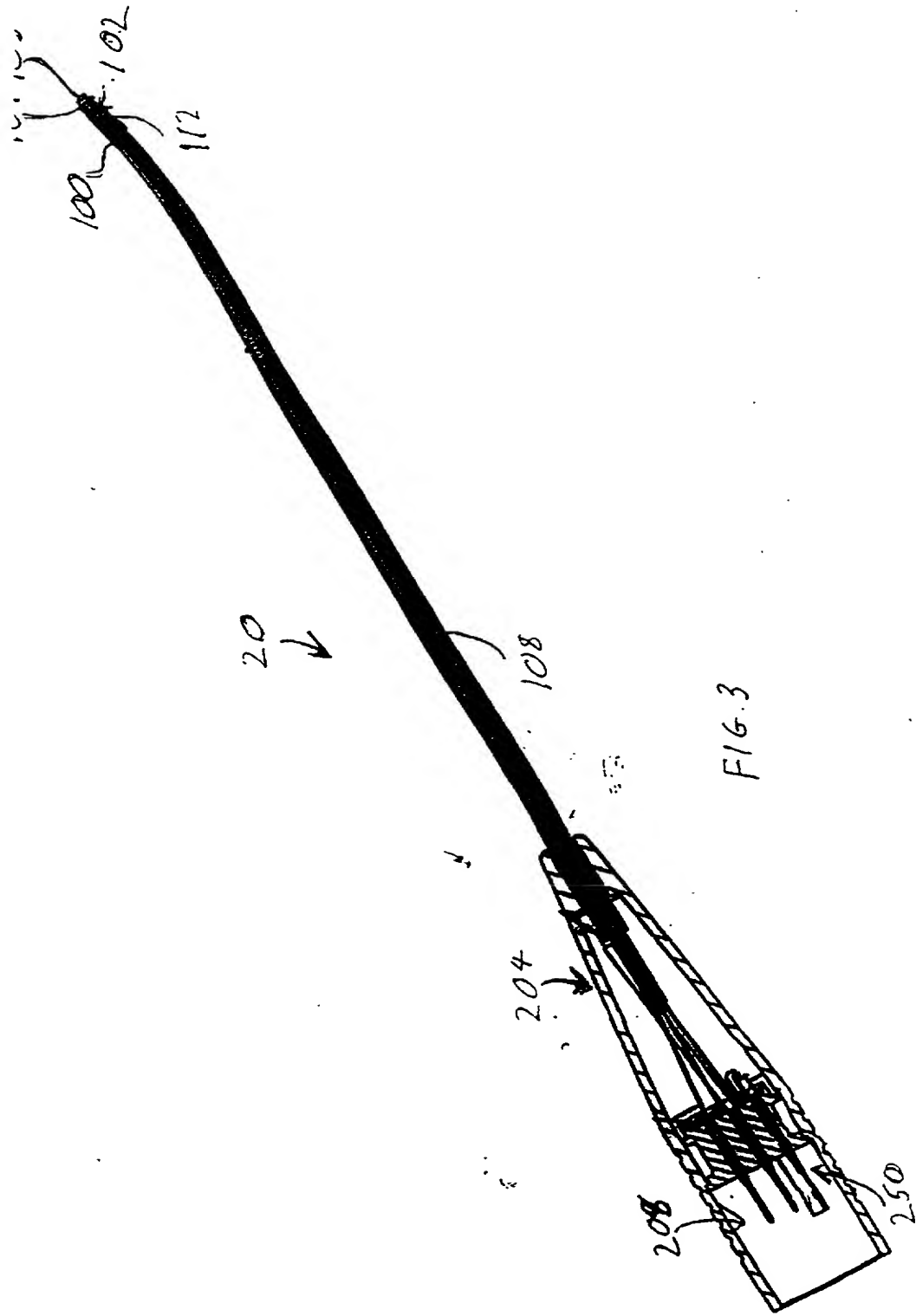


FIG. 1





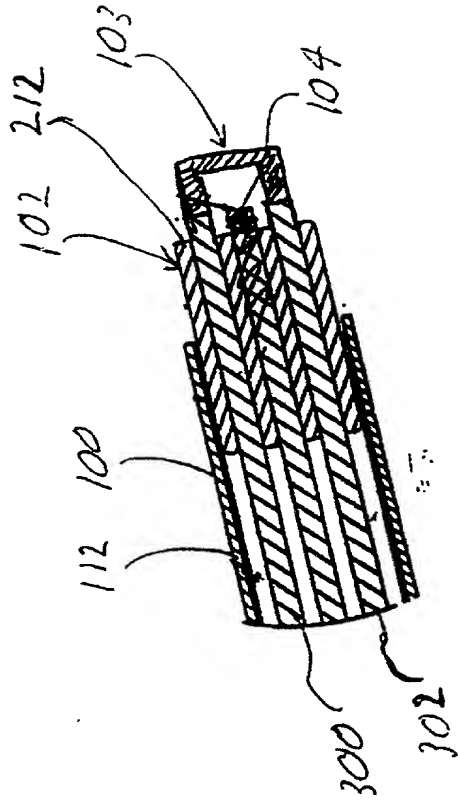


FIG. 4

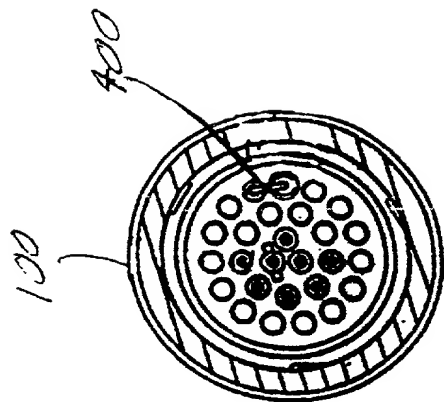


FIG. 5A

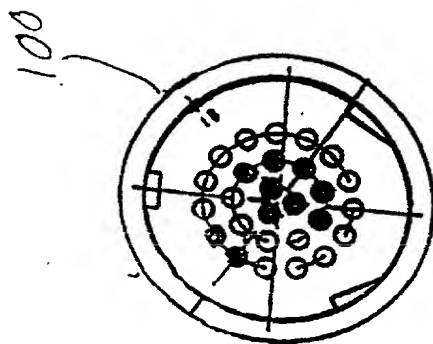


FIG. 5B



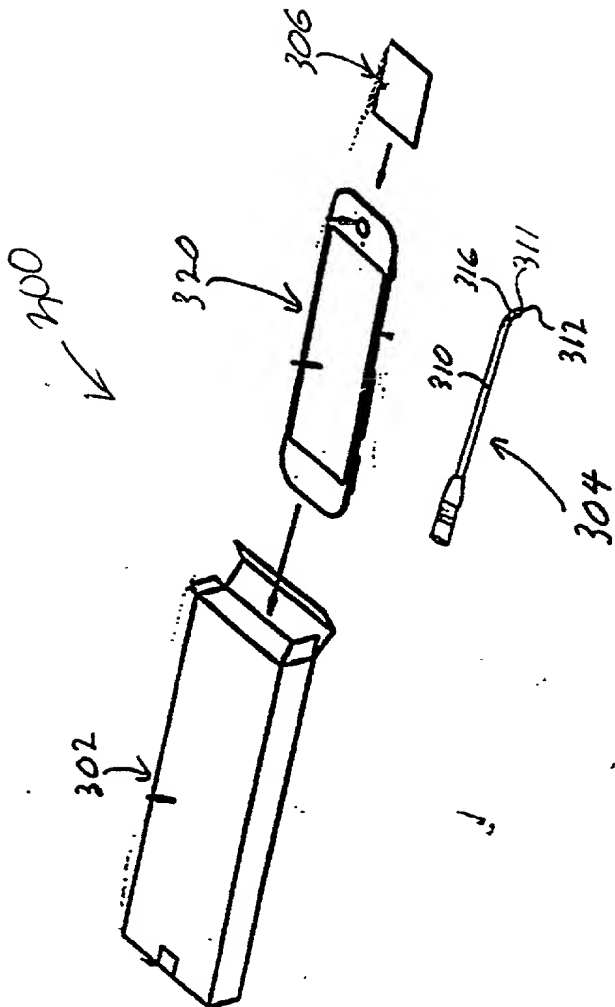
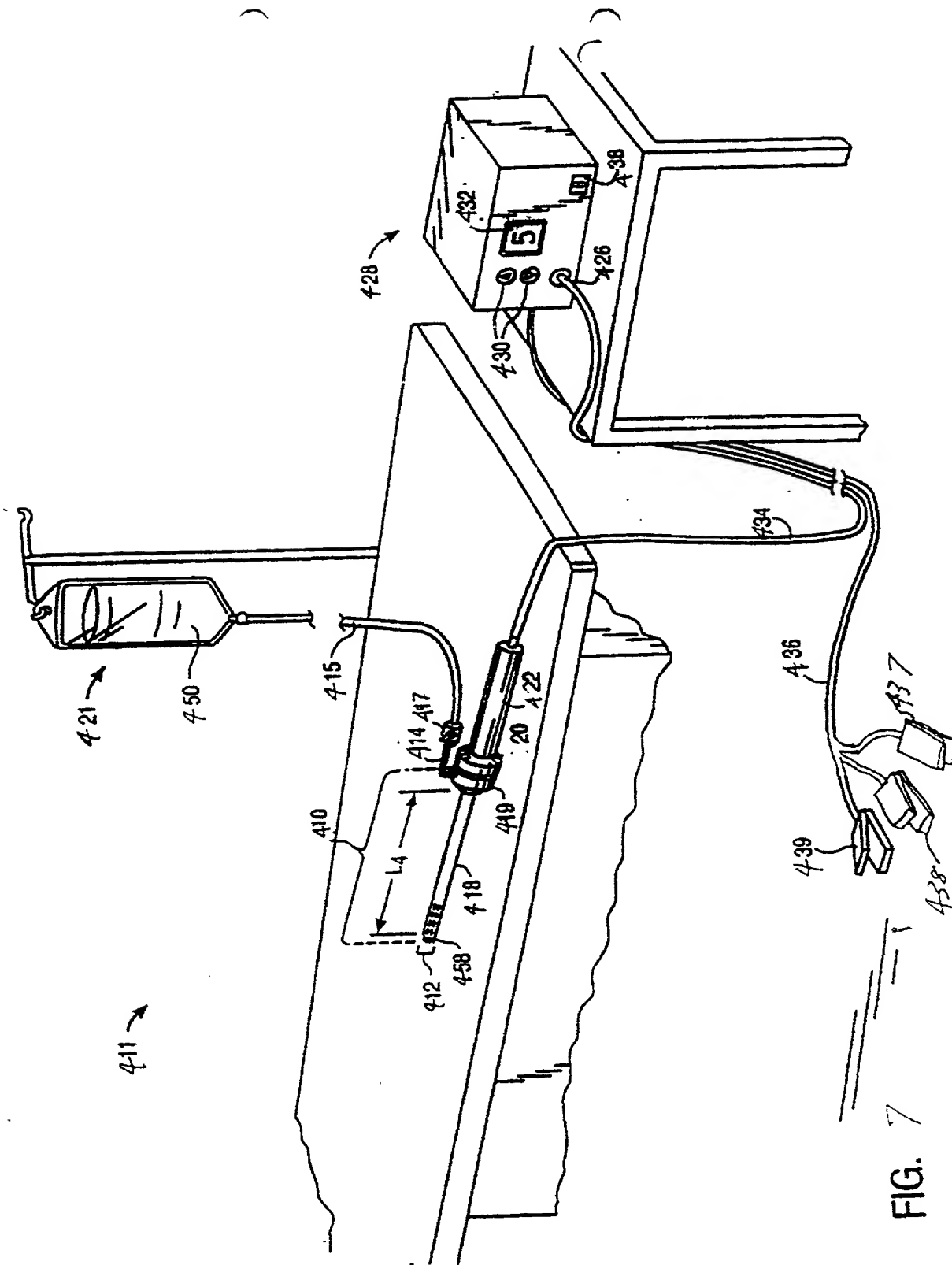
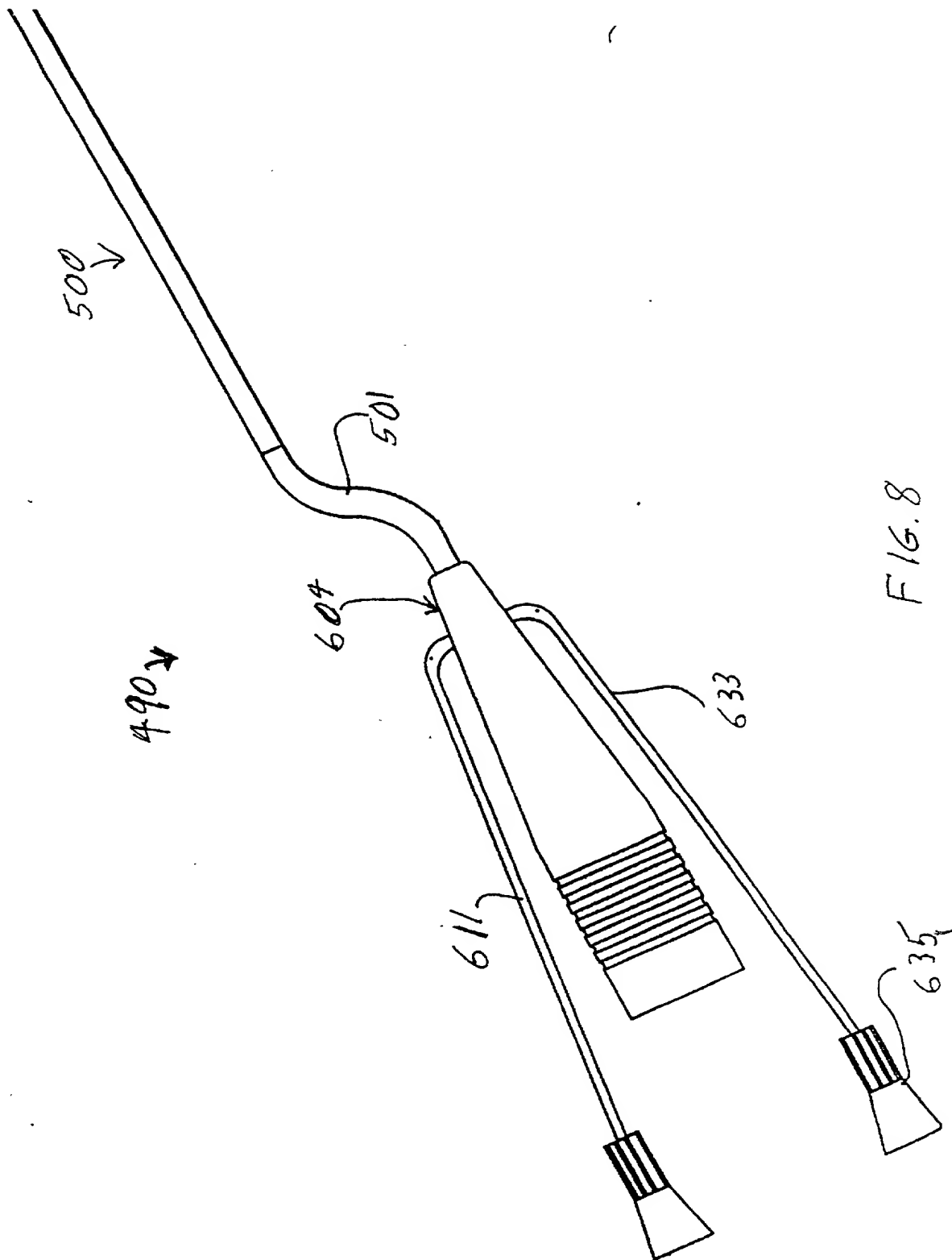


FIG. 6





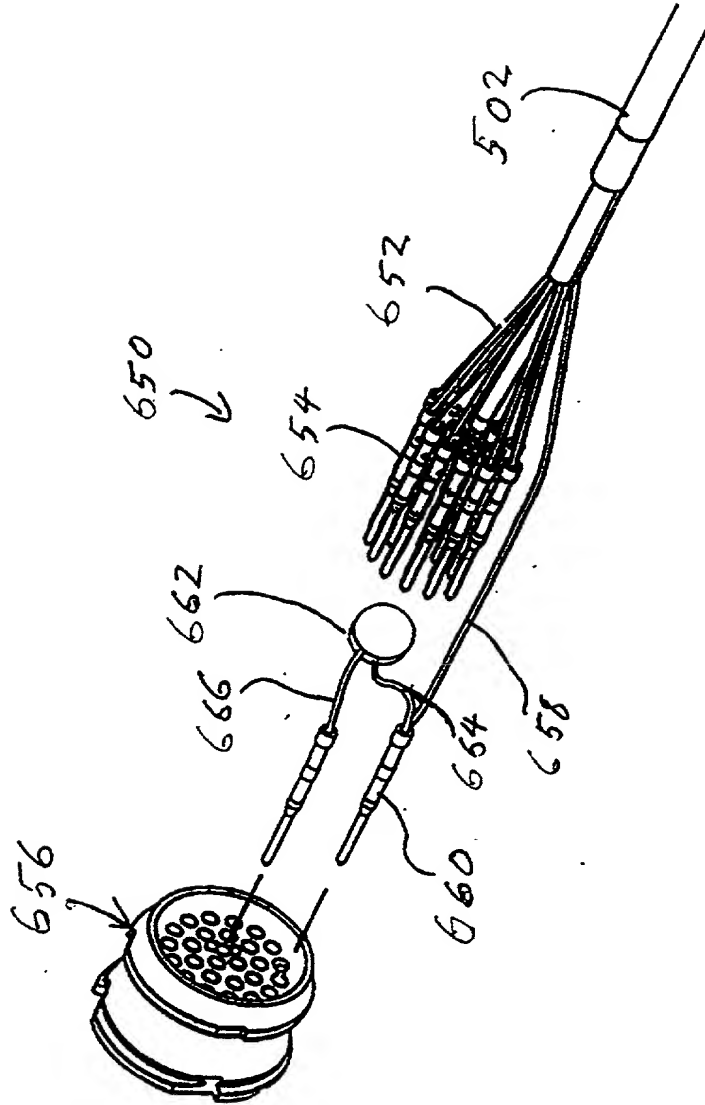


FIG. 10

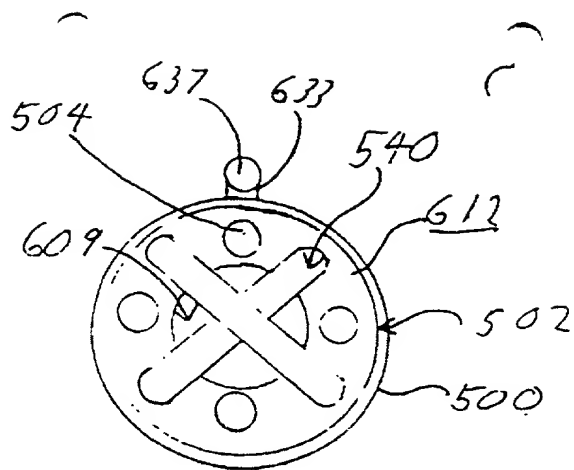


FIG. 9

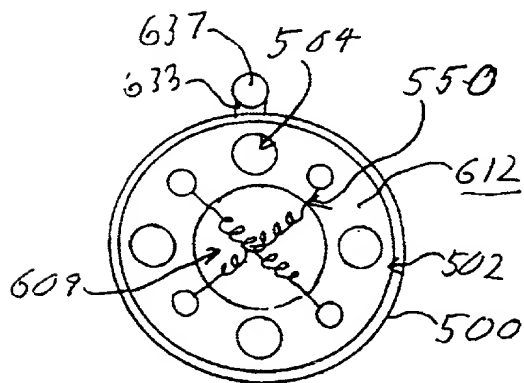


FIG. 11.

09709035 110800

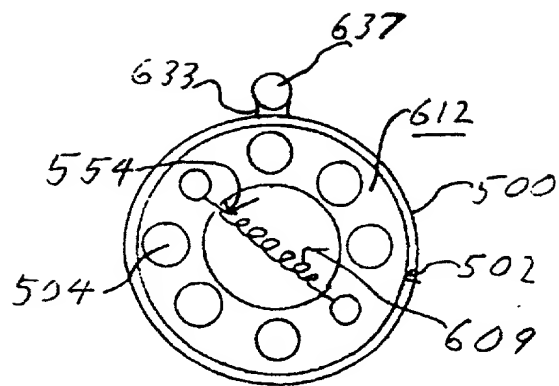
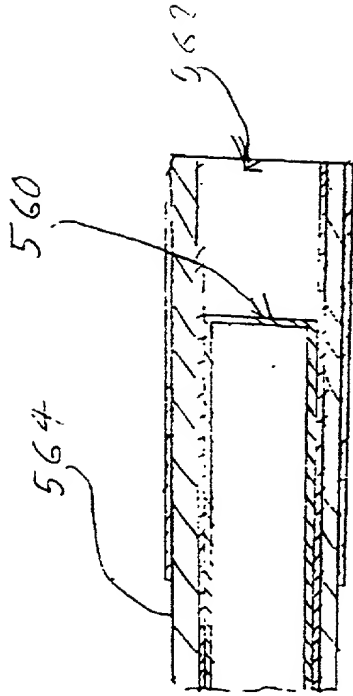


FIG. 12

09/09035, 110800



490 →

F16 13

09709035, 110800



FIG 14



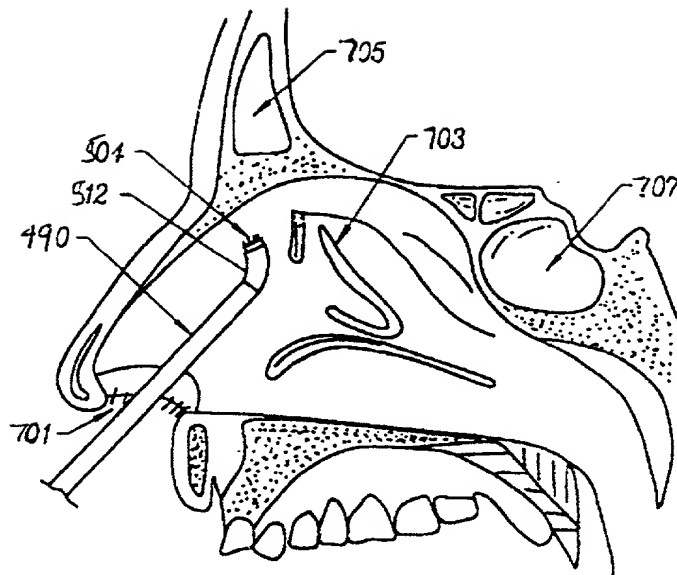


FIG. 15

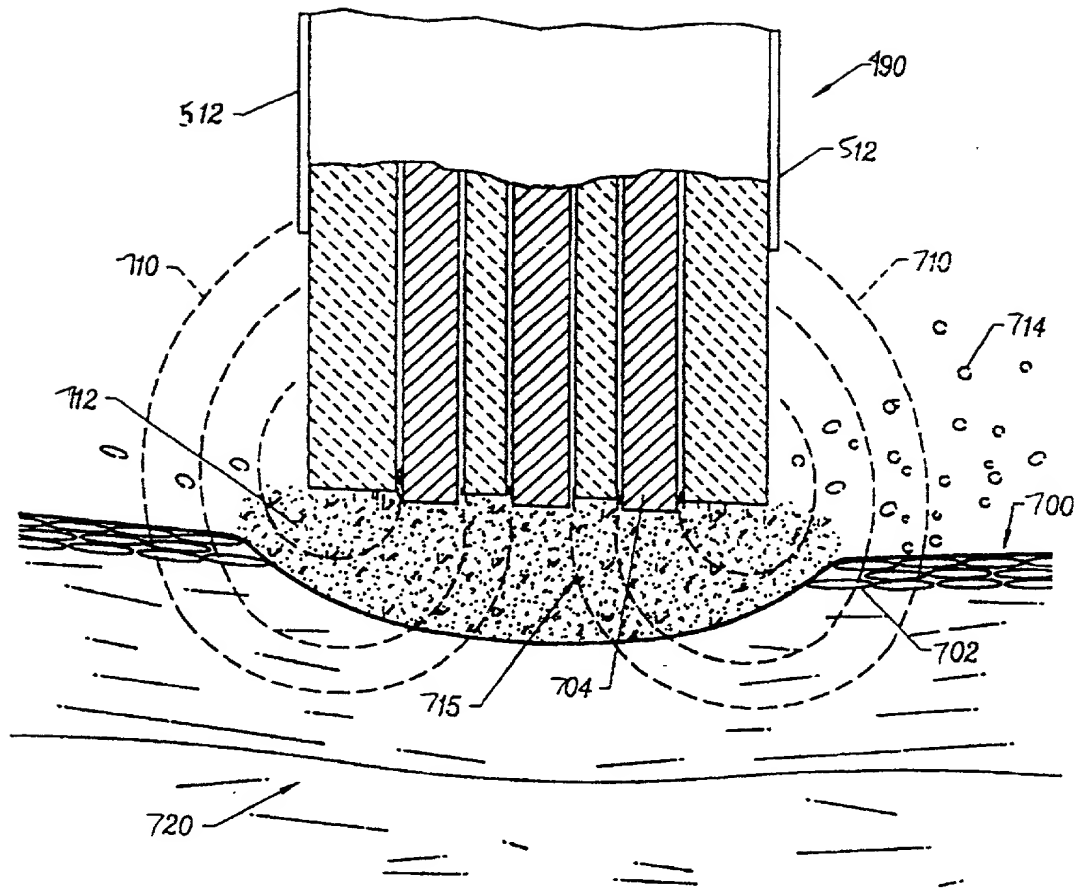


FIG. 16A

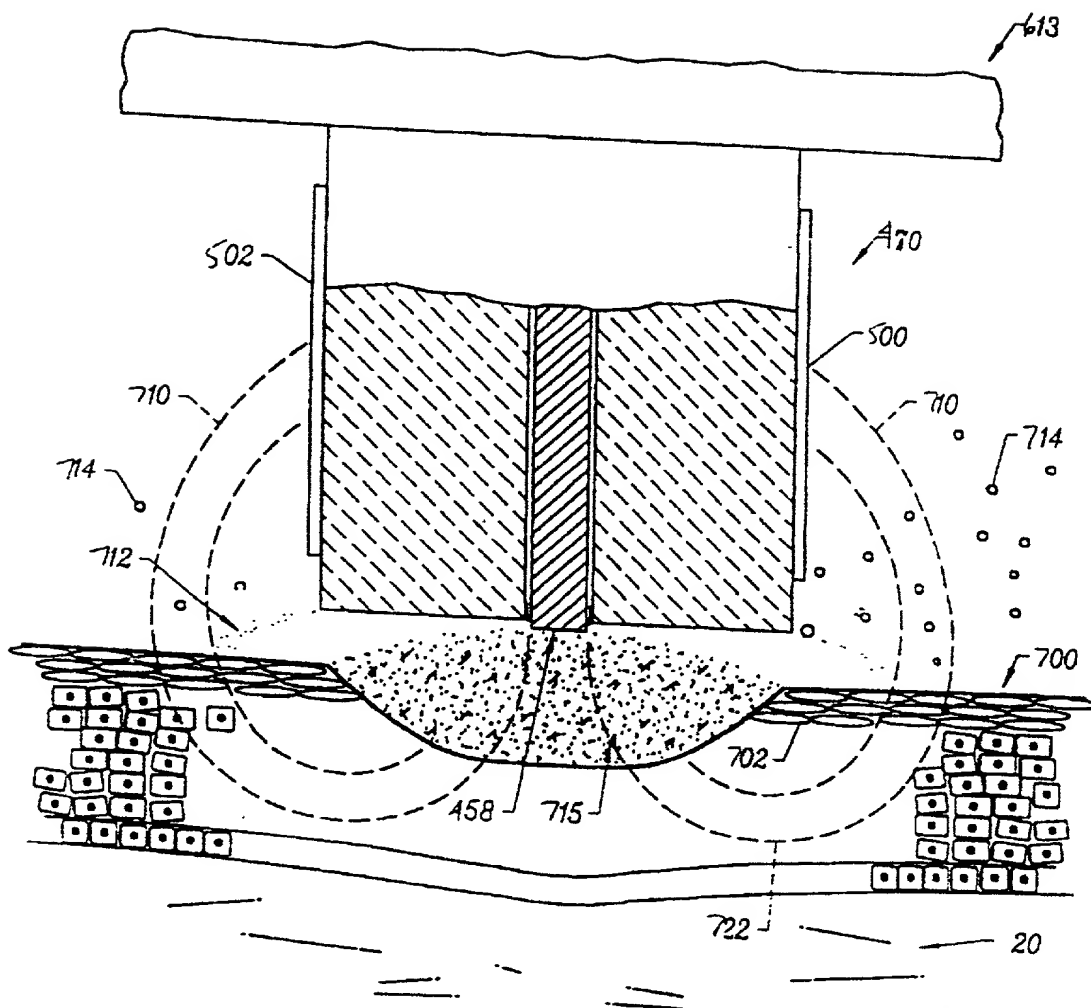


FIG. 16B

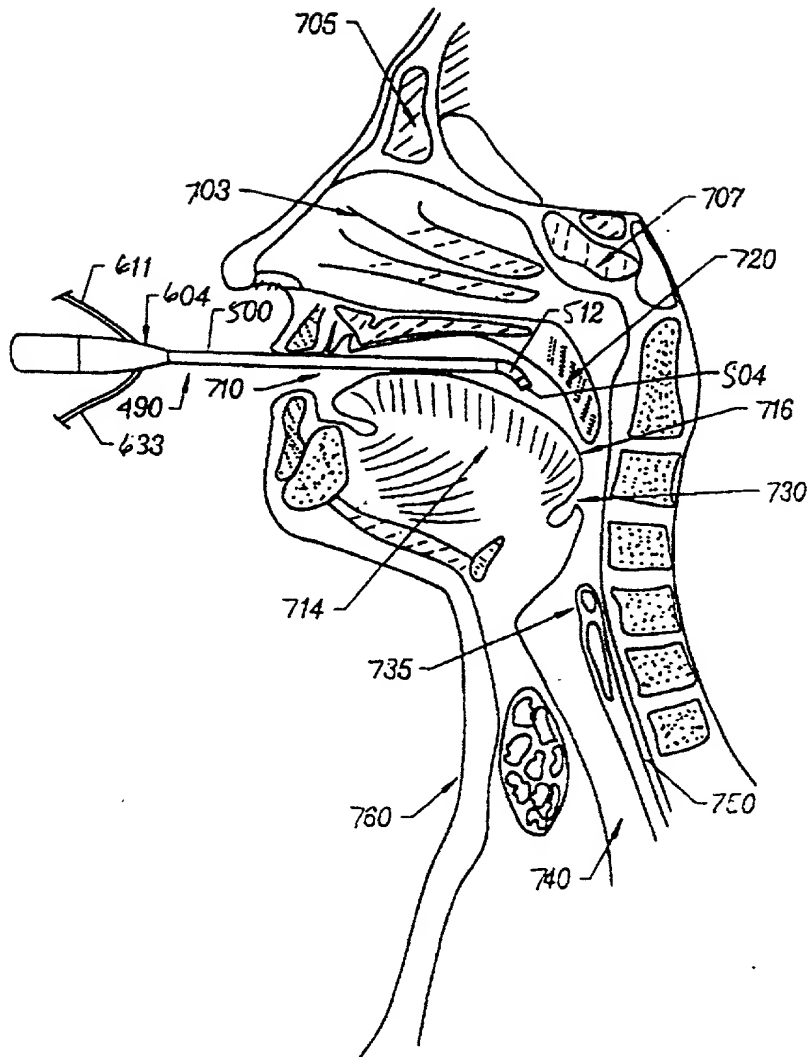
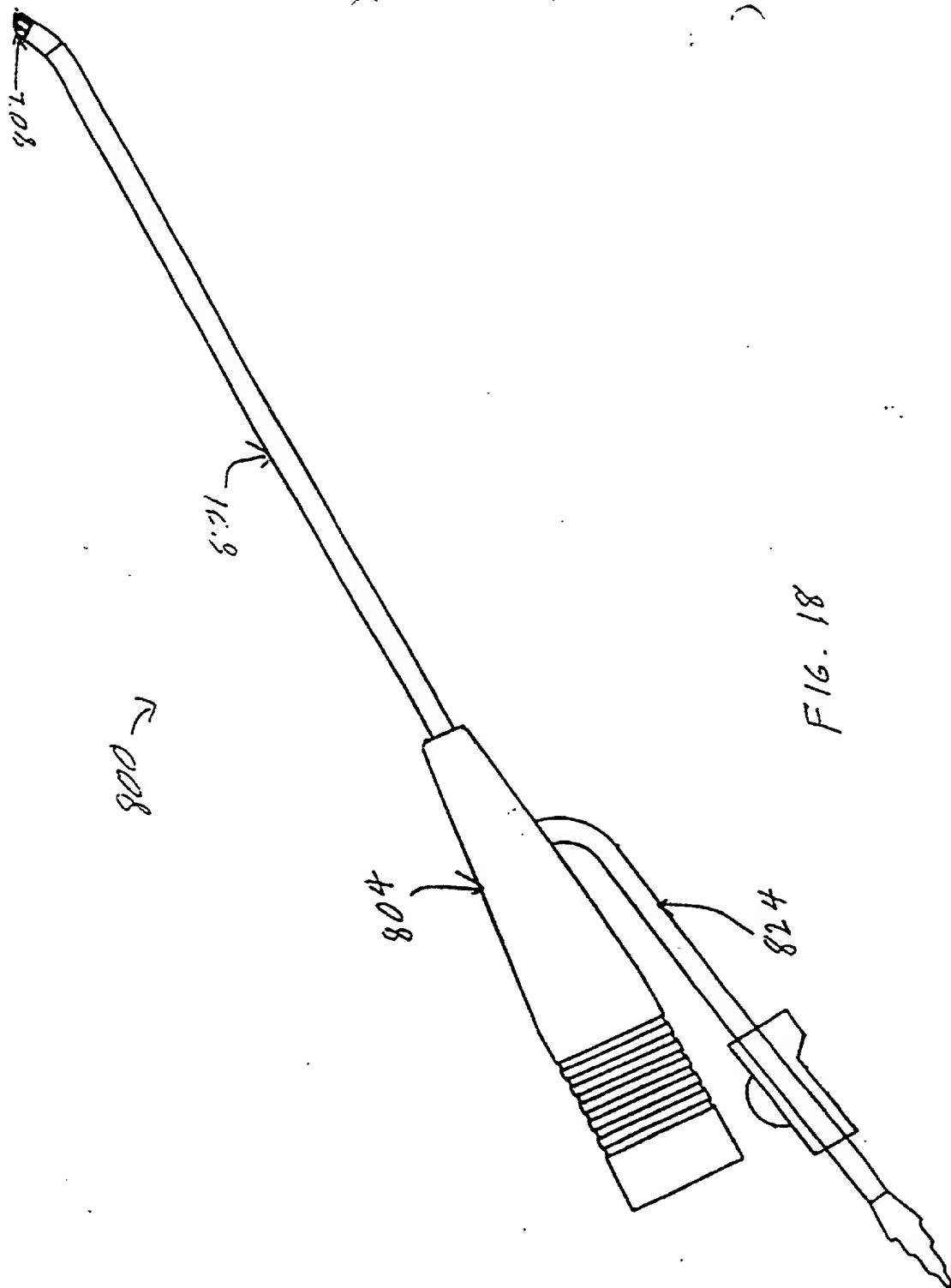
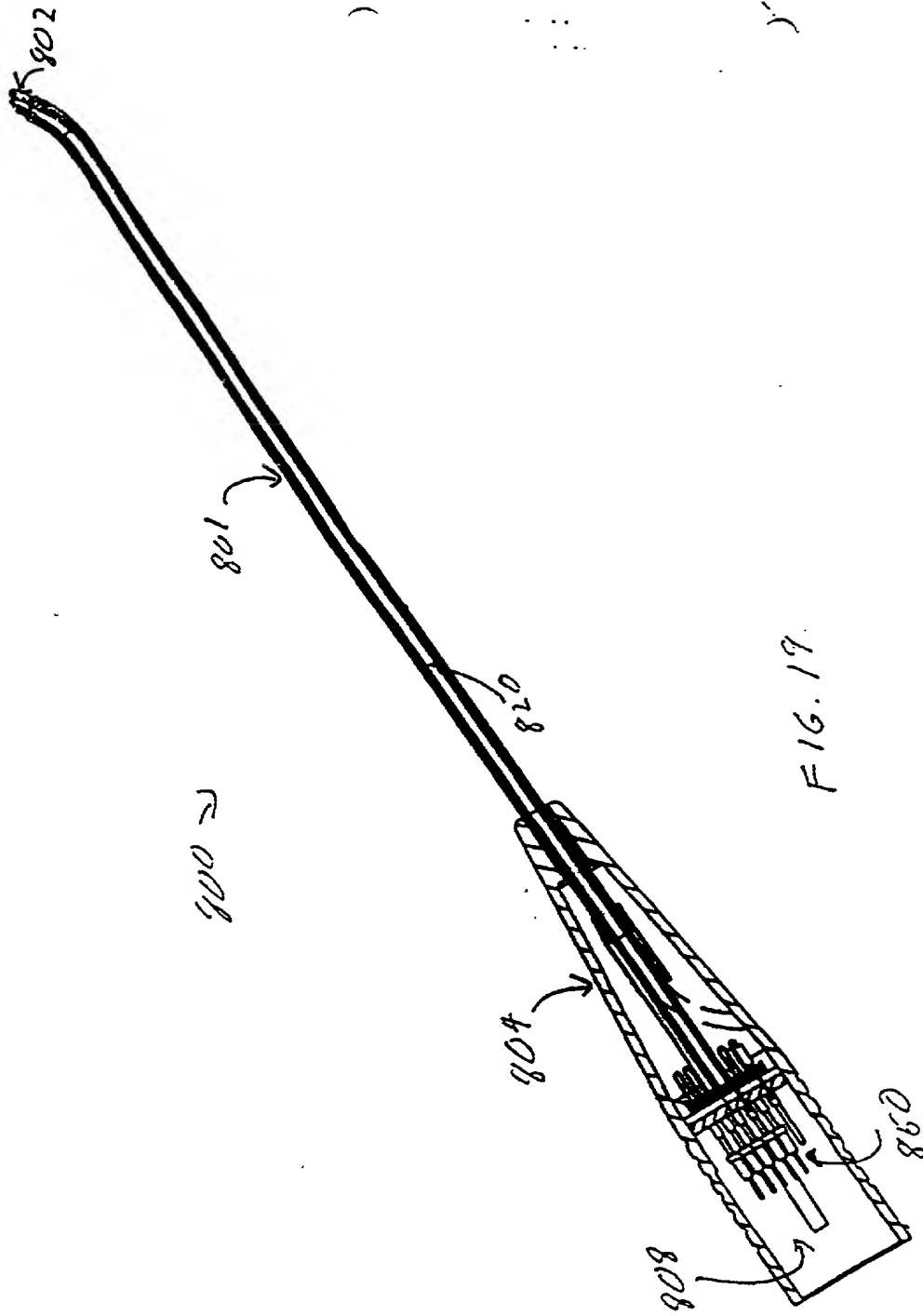


FIG. 17





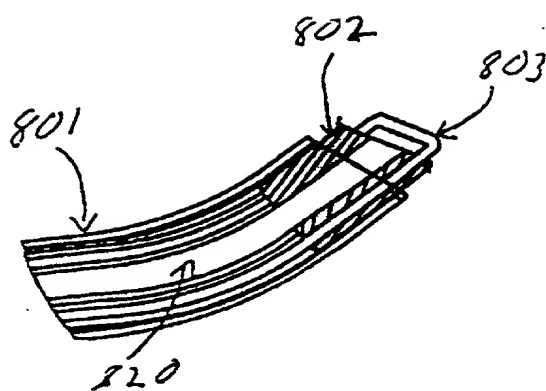


FIG. 20

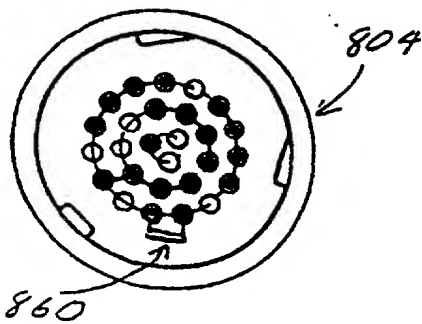


FIG. 21

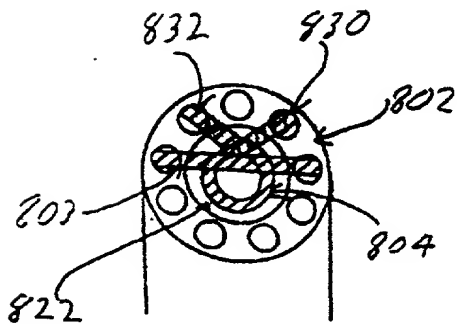


FIG. 22

09/09035-110300



09/09/03 11:08:00

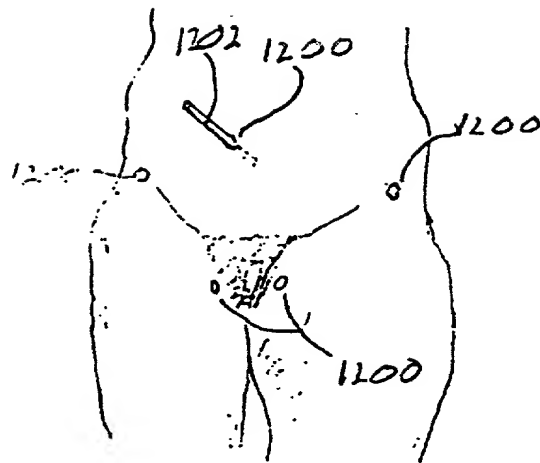


FIG. 23

09709035, 110800

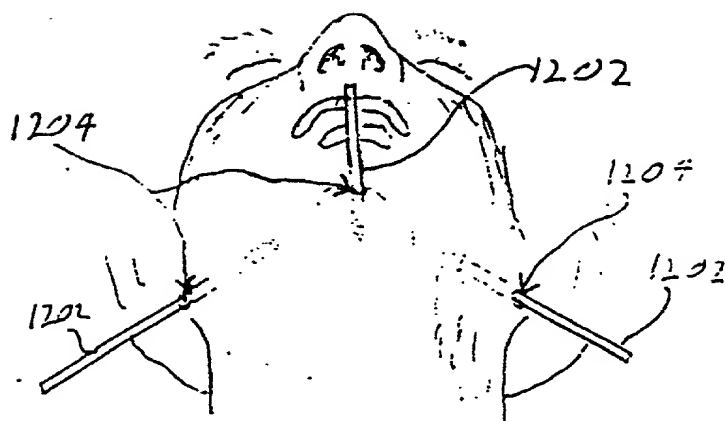
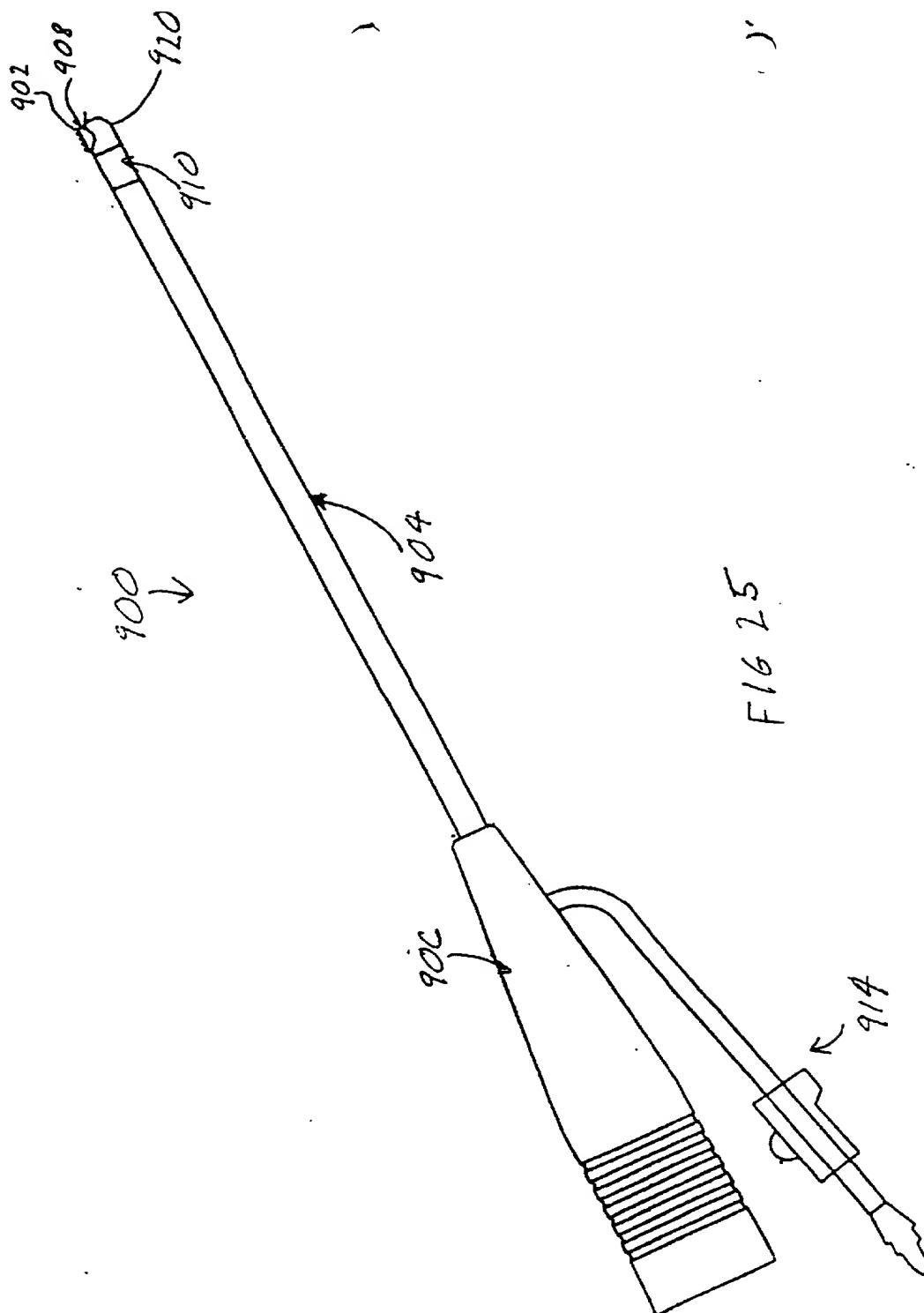


FIG 24



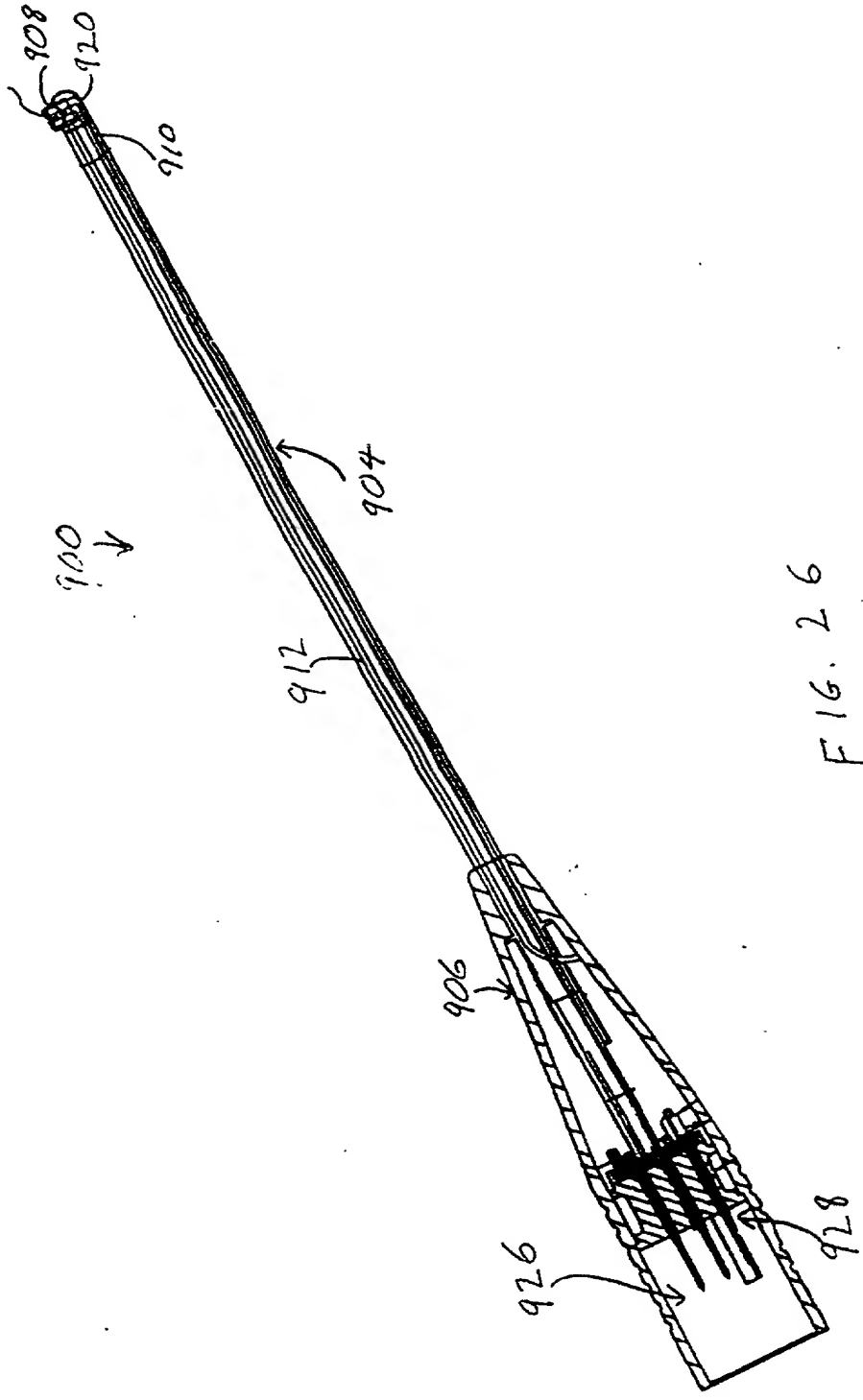


FIG. 26

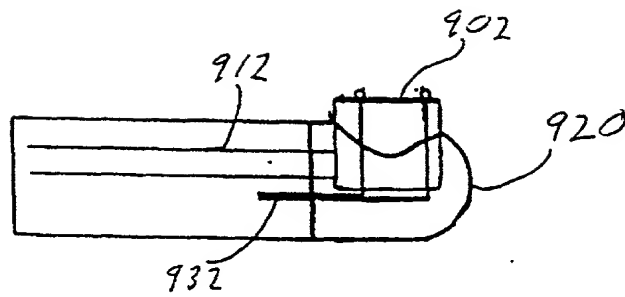


FIG. 27

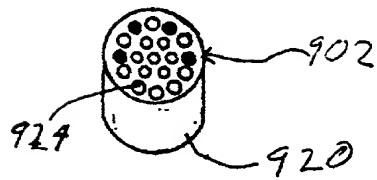


FIG 28

09709035-110800

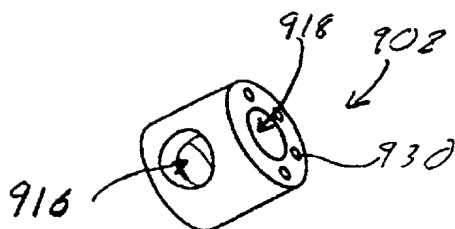


FIG. 29

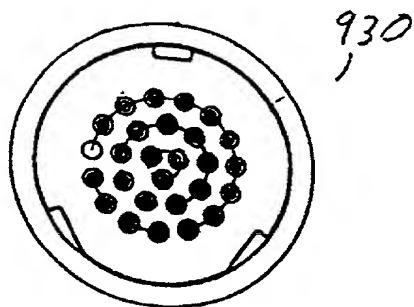


FIG. 30

09/14/2000 13:05 925--833--2547

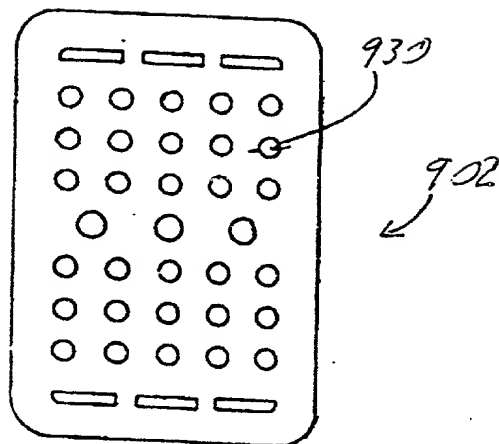


FIG. 31

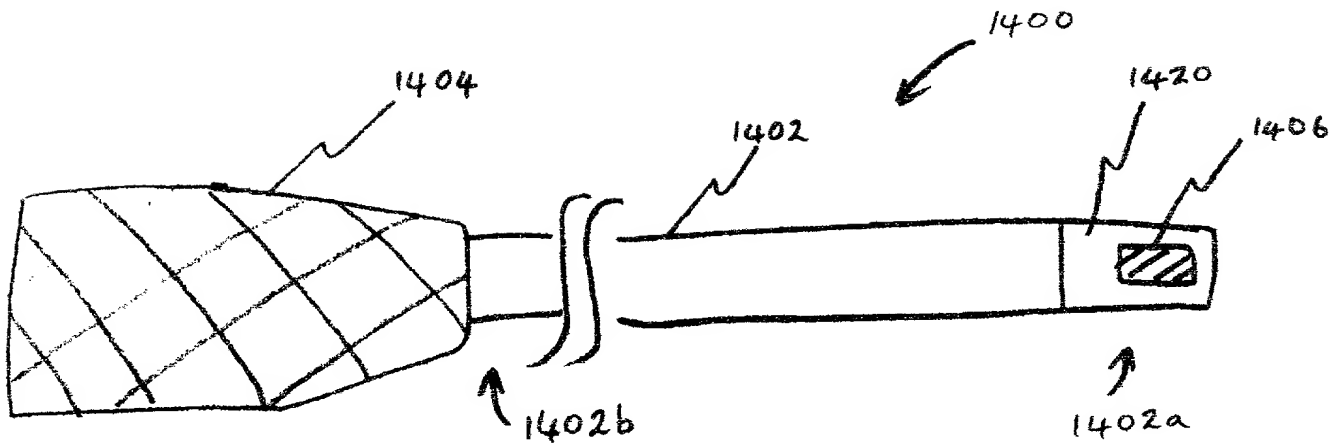


FIG. 32

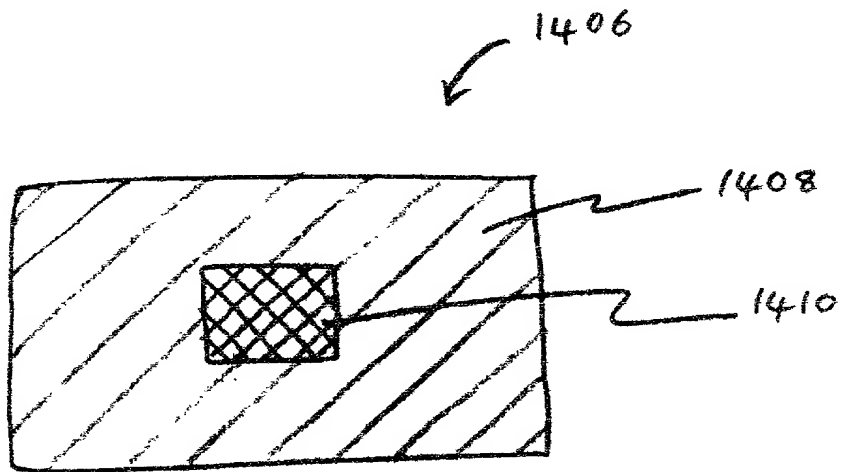


FIG. 33



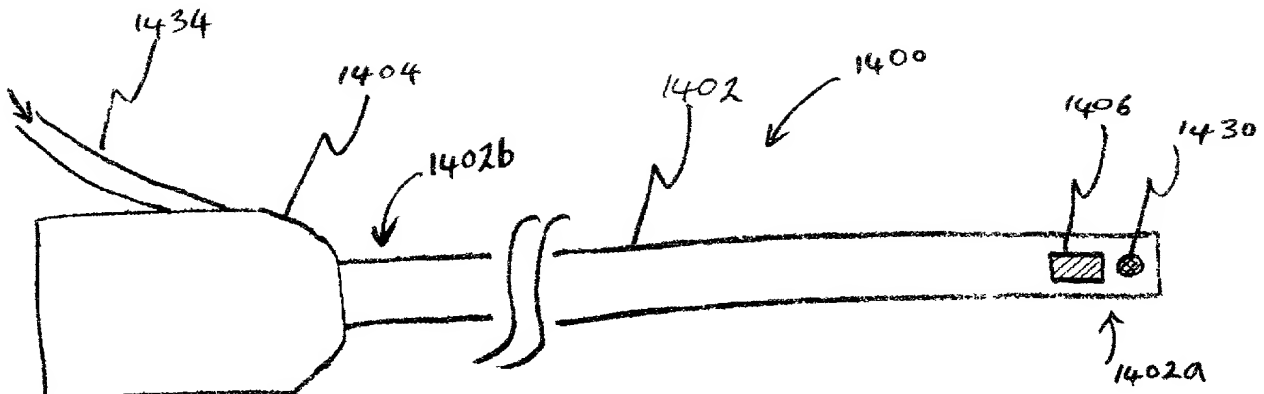


FIG. 34A

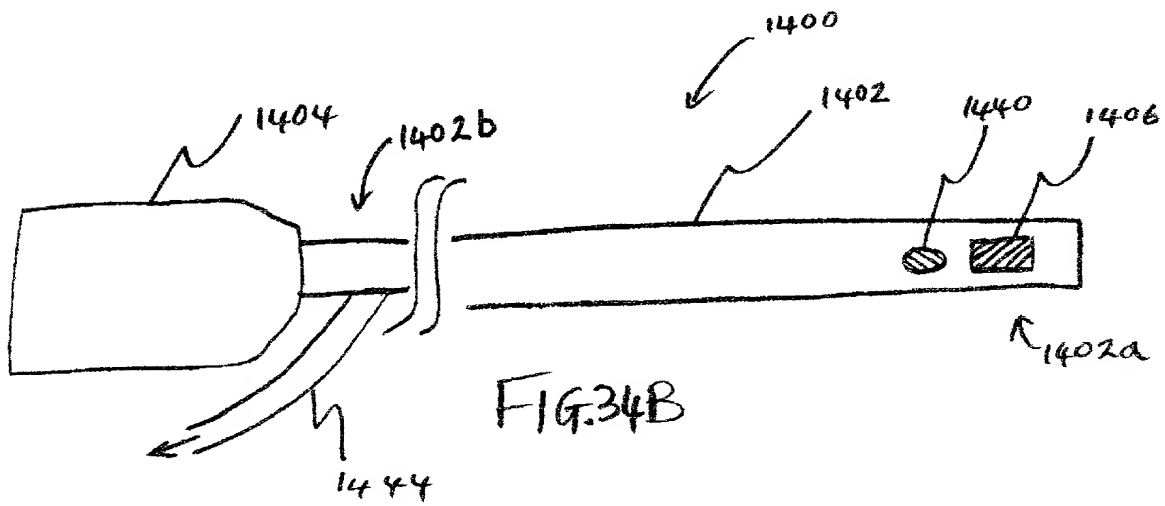


FIG. 34B

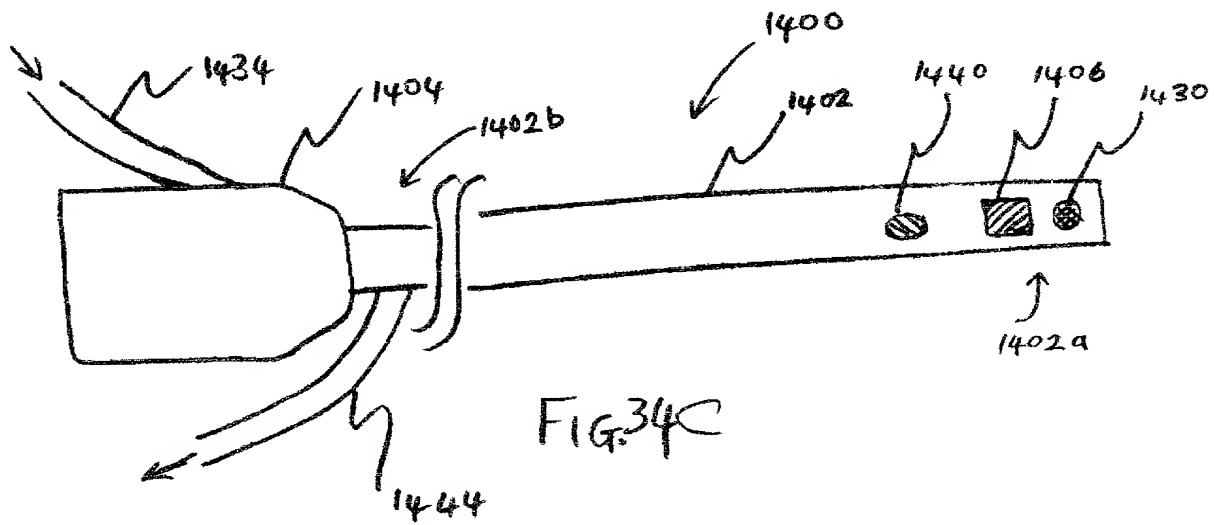
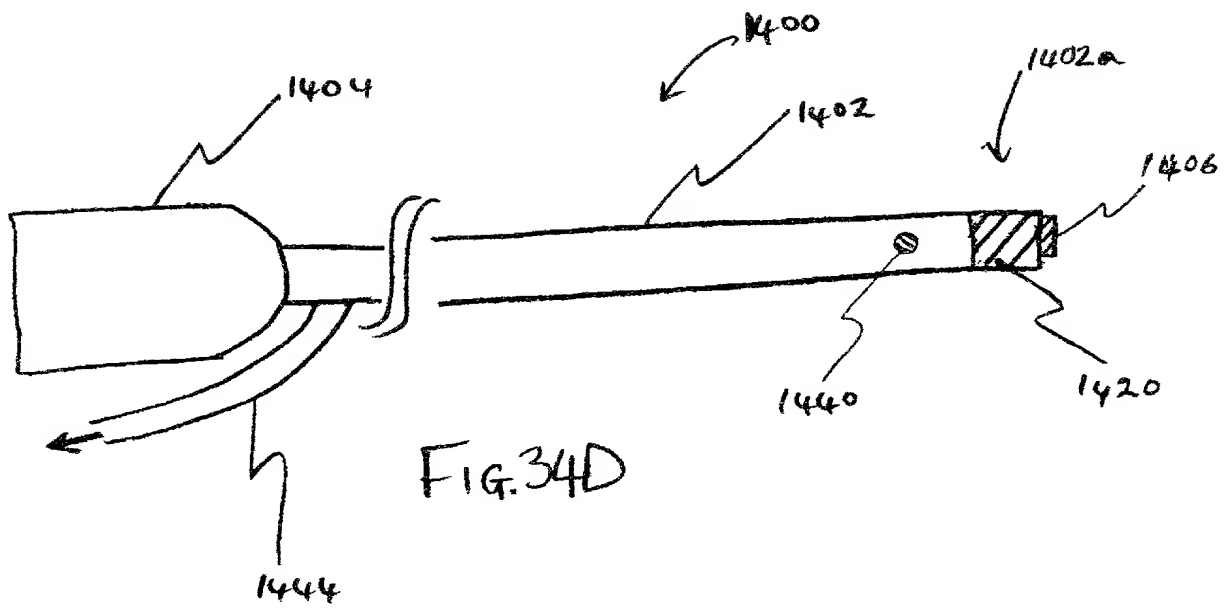
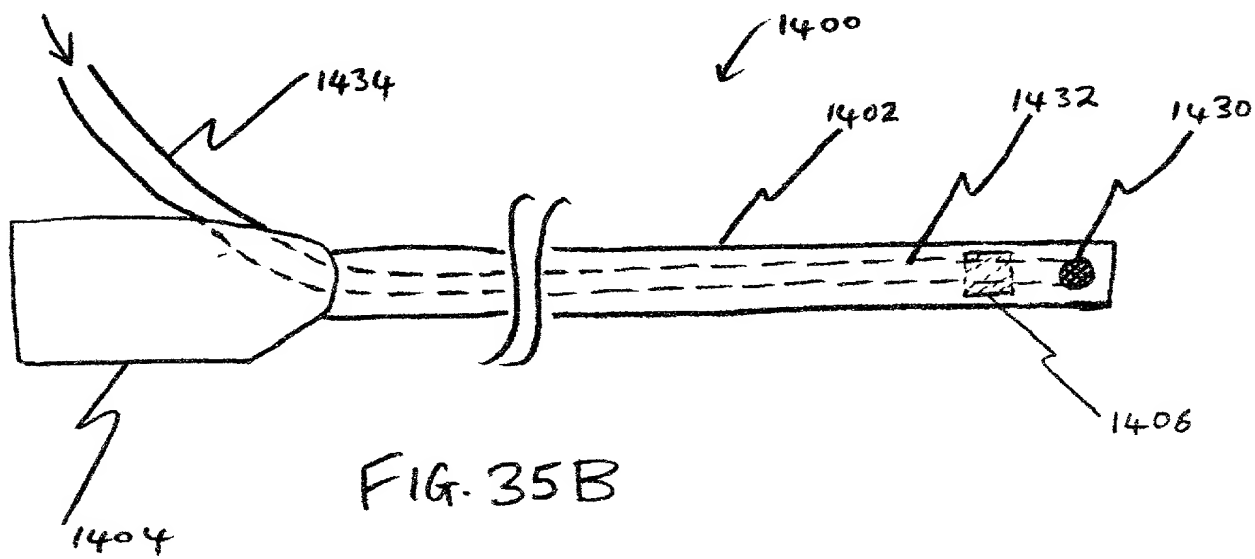
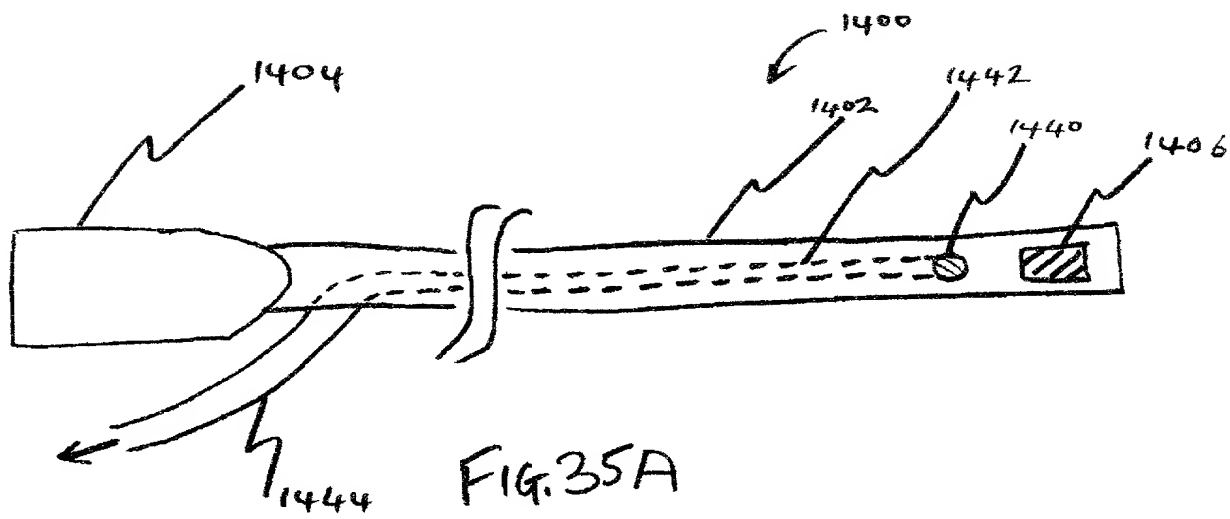


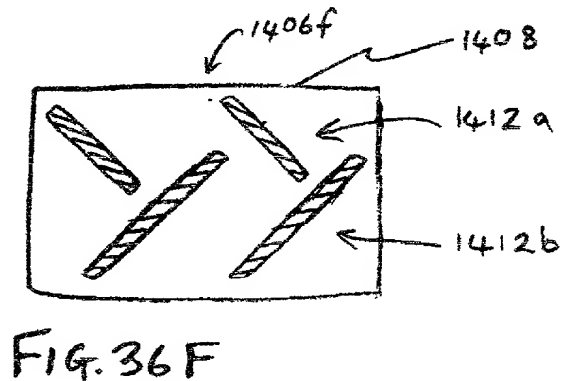
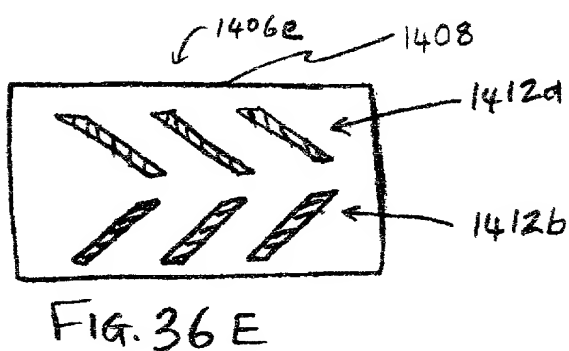
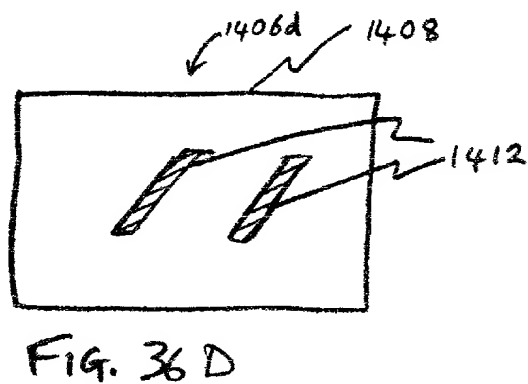
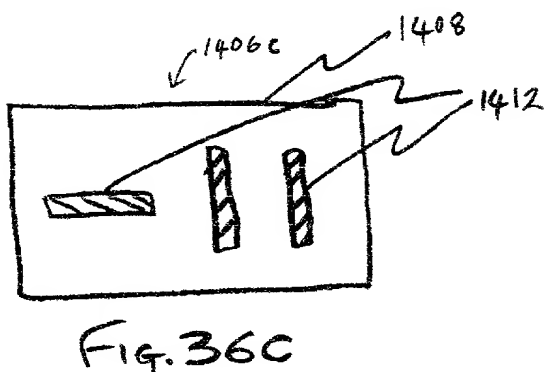
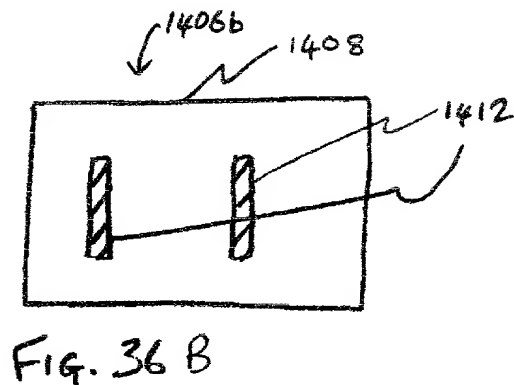
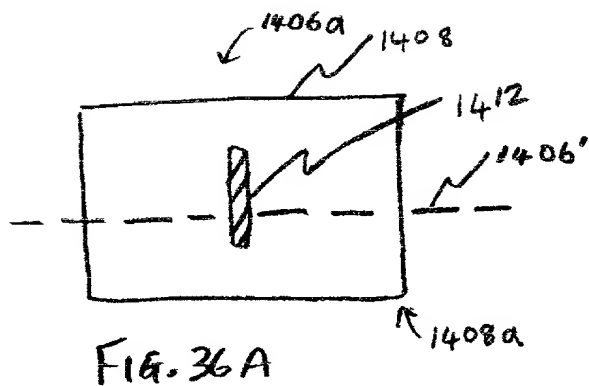
FIG. 34C



09709035, 110800

09/29/2008 11:00:00





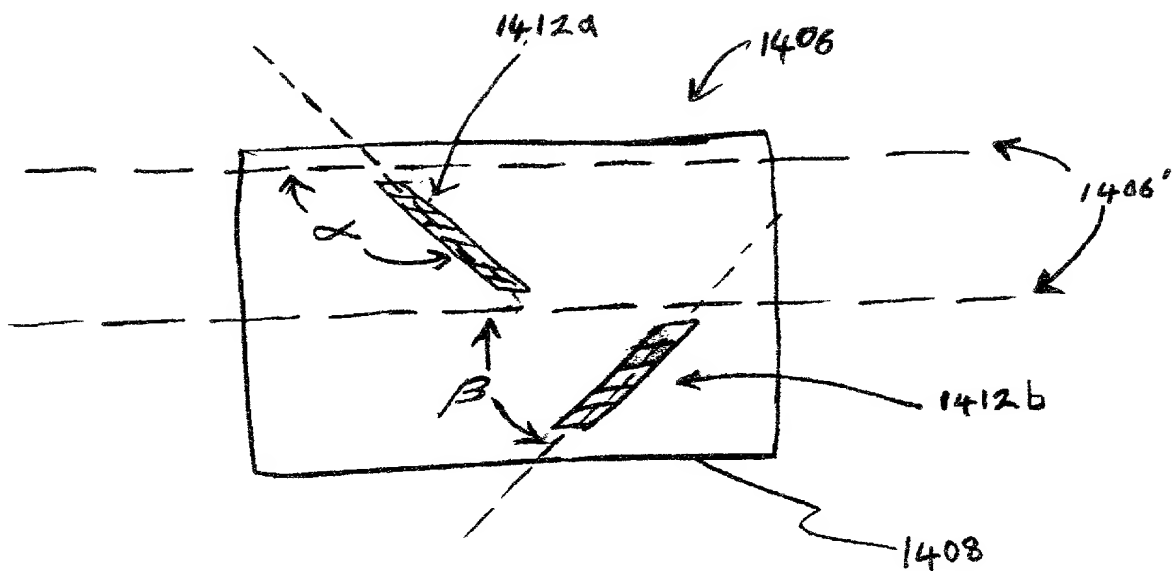


FIG. 37

09709035, 110800

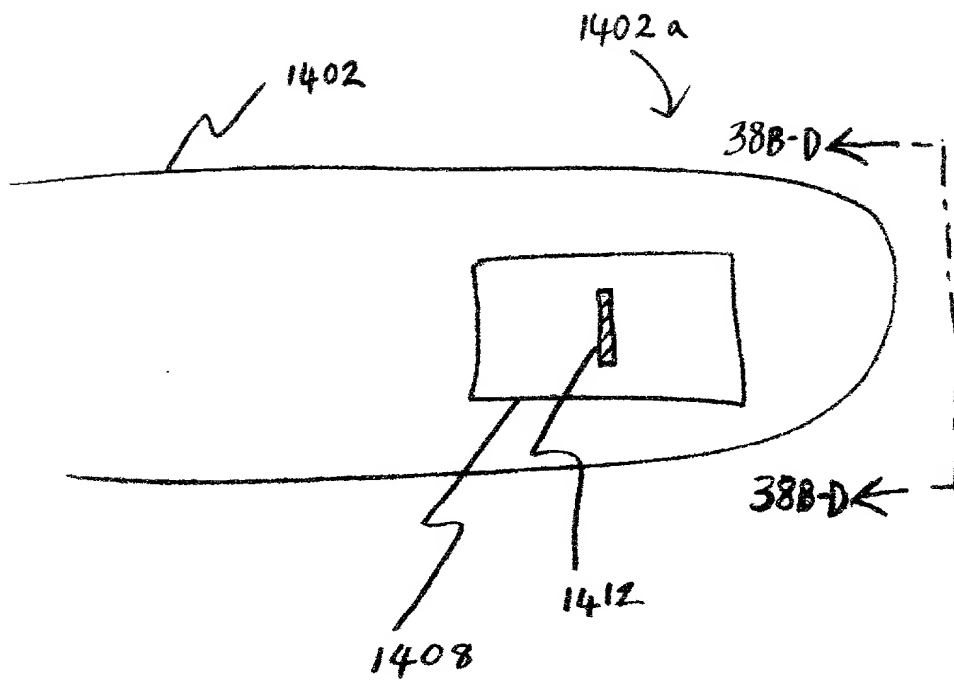


FIG. 38A

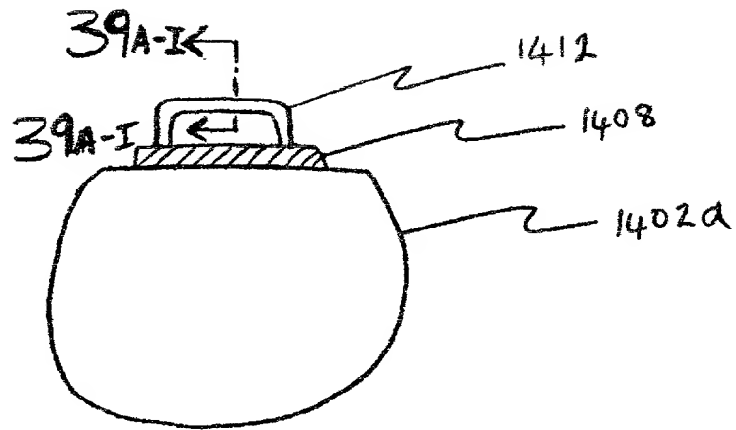


FIG. 38B

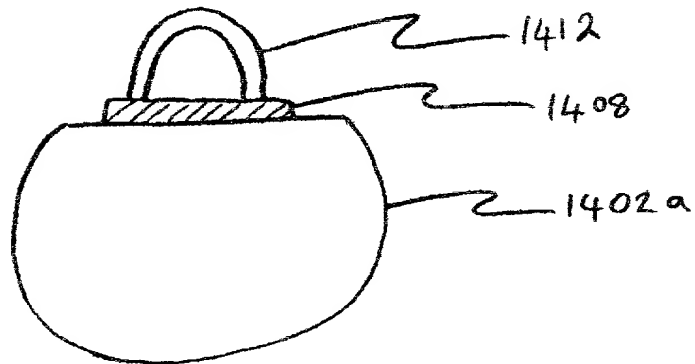


FIG. 38C

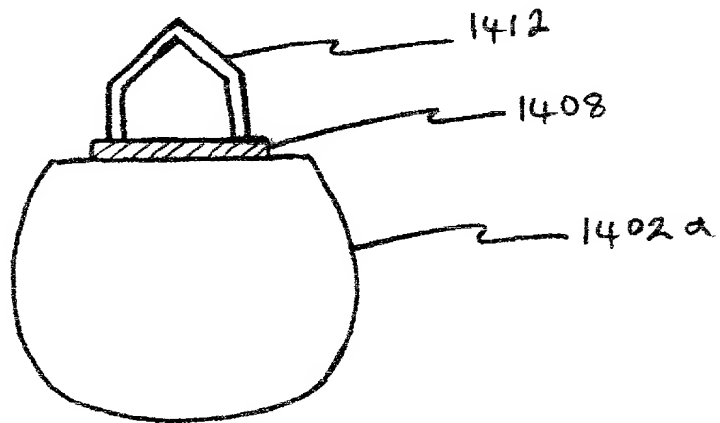


FIG. 38D

09709035-110800

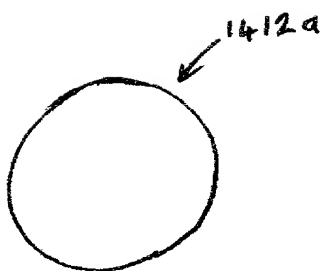


FIG. 39A

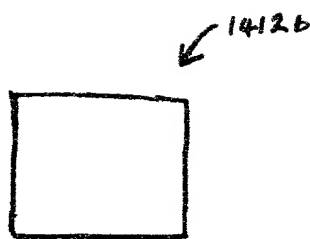


FIG. 39B

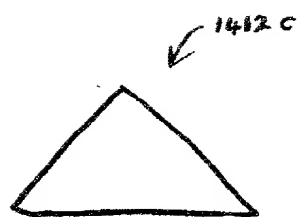


FIG. 39C

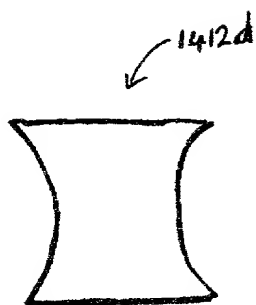


FIG. 39D

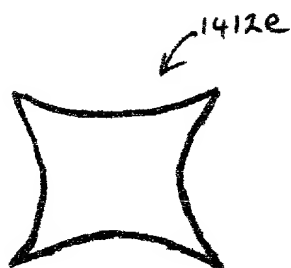


FIG. 39E

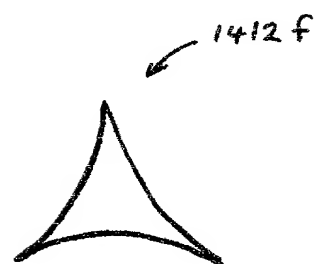


FIG. 39F

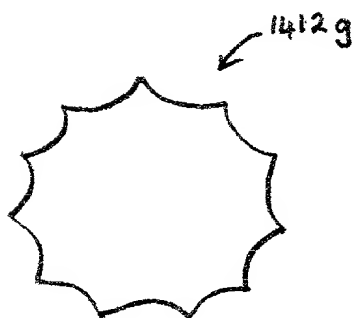


FIG. 39G

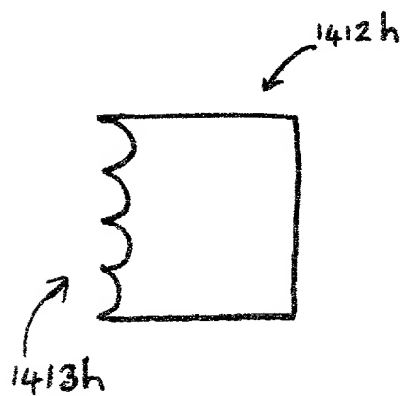


FIG. 39H

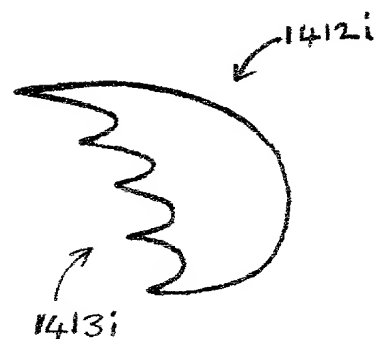


FIG. 39I

09709035, 110800



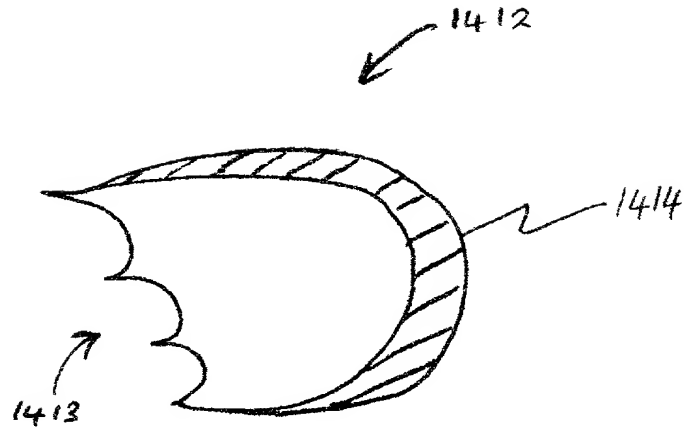
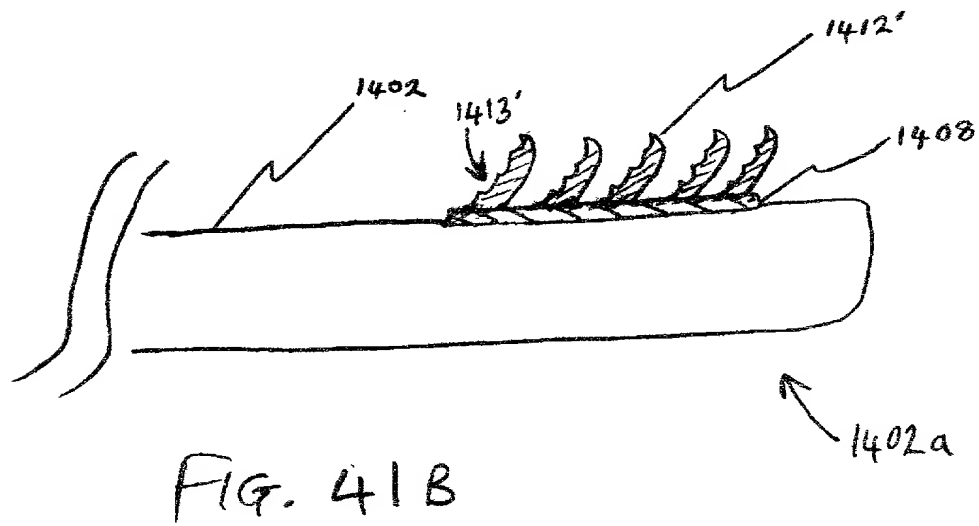
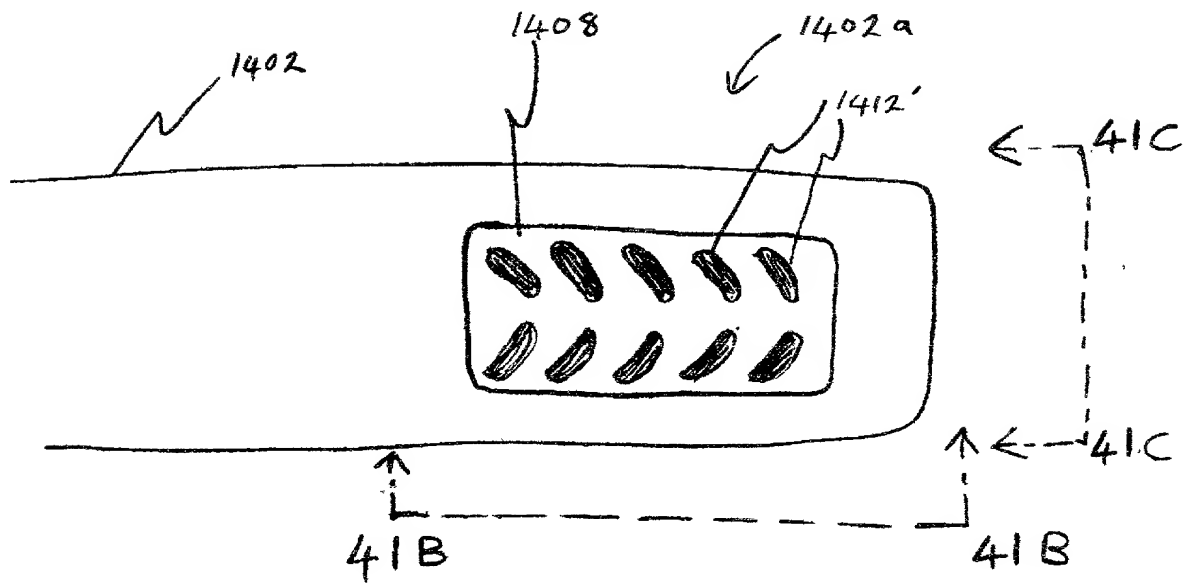


FIG. 40

09709035.110800



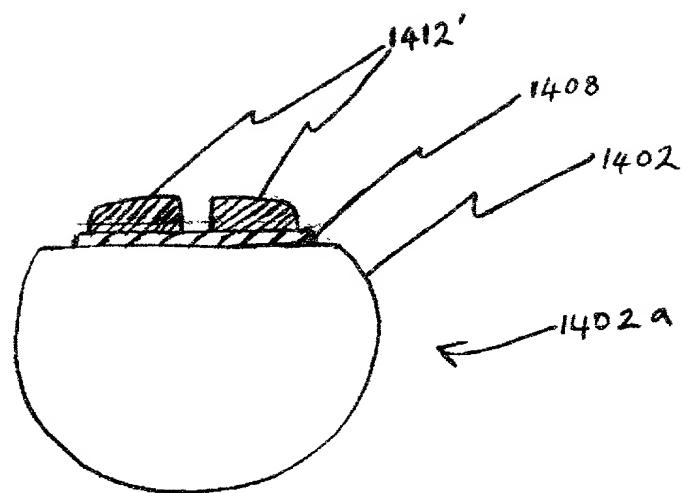
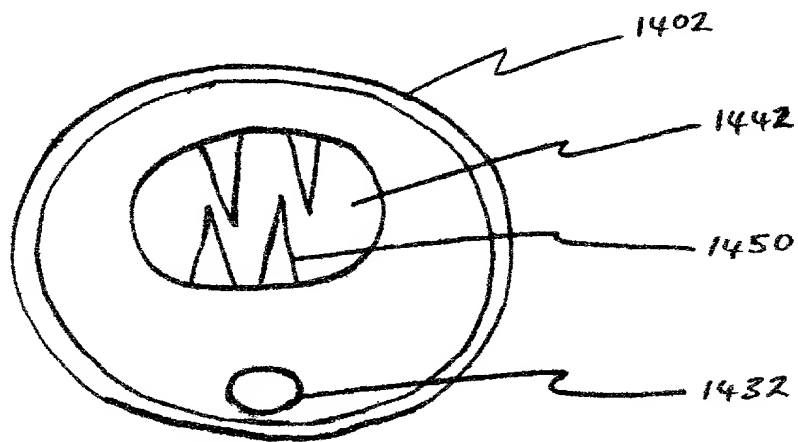
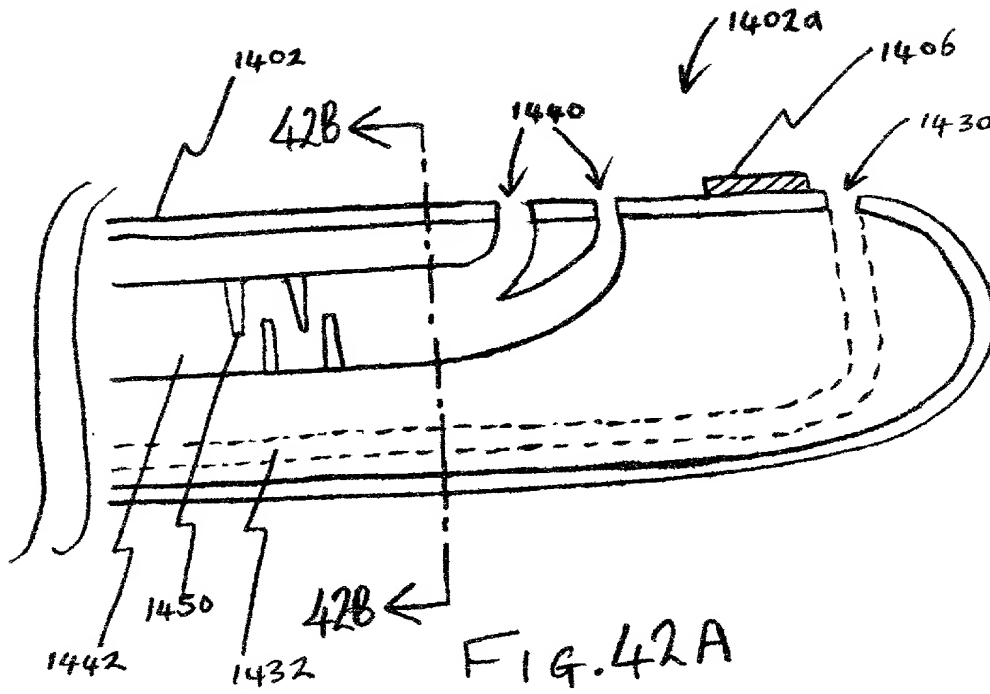


FIG. 41C

09/29/2000 09:50 925--833--2547



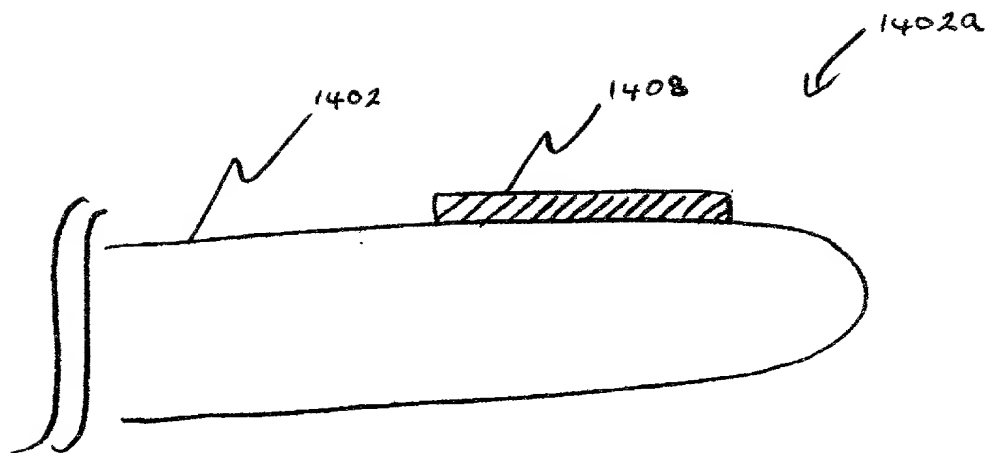


FIG. 43A

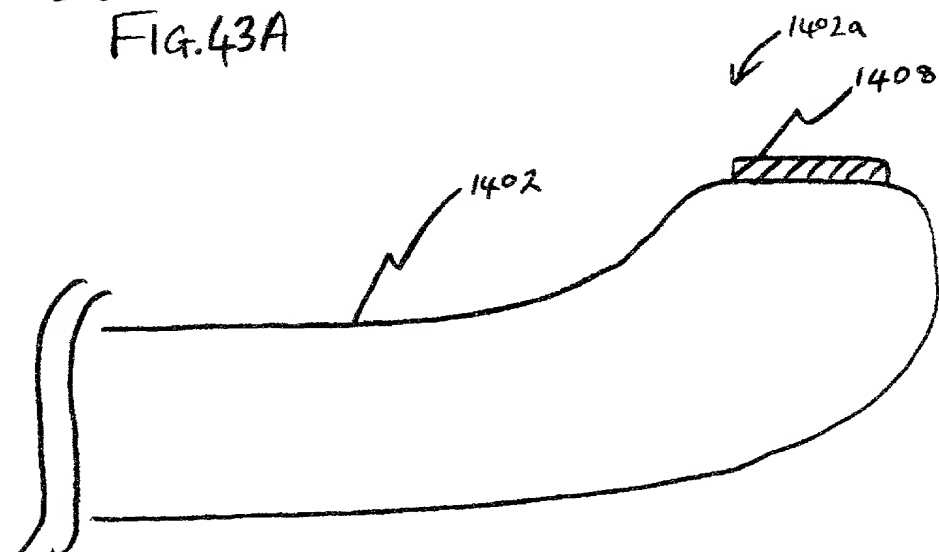


FIG. 43B

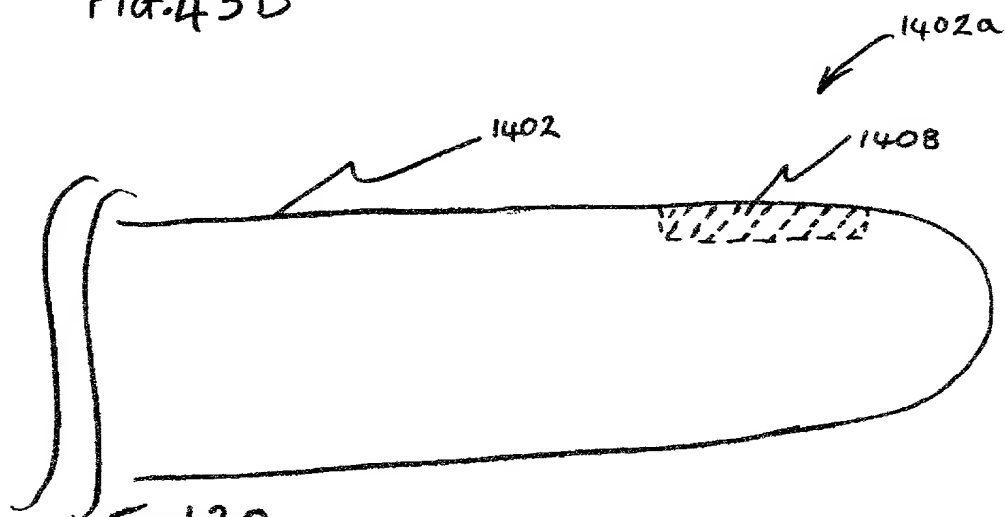


FIG. 43C

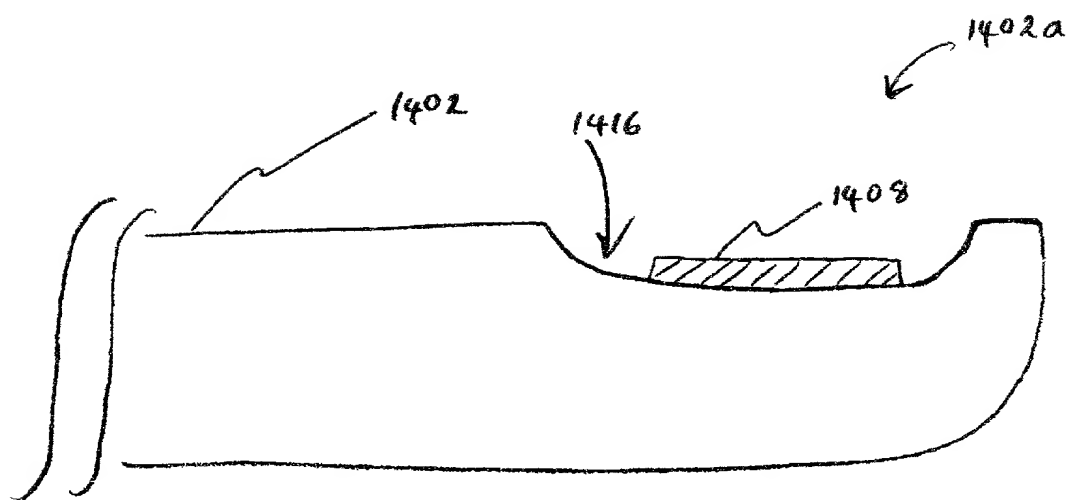
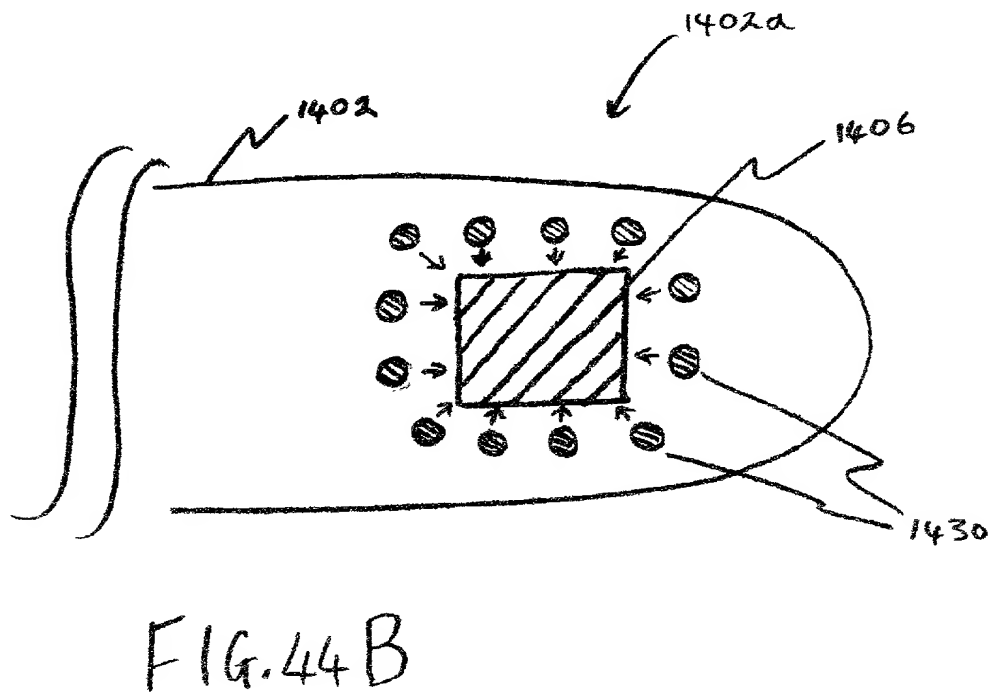
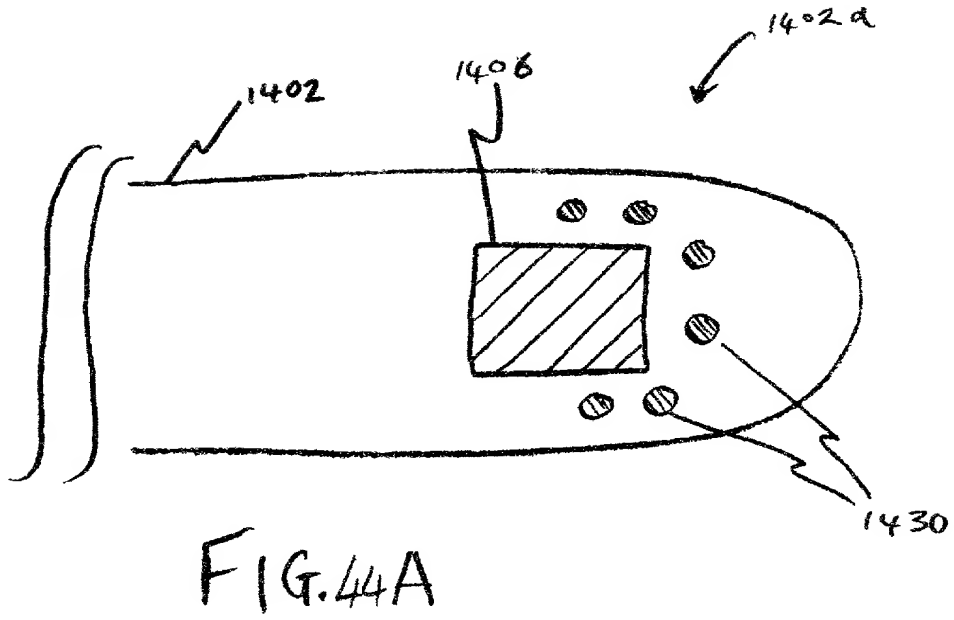


FIG. 43D



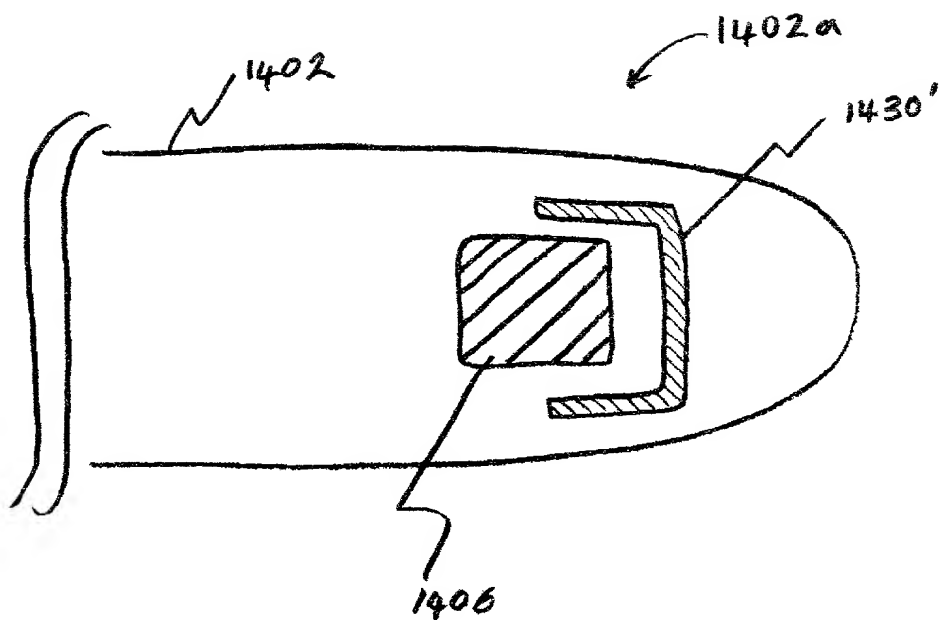


FIG. 44C

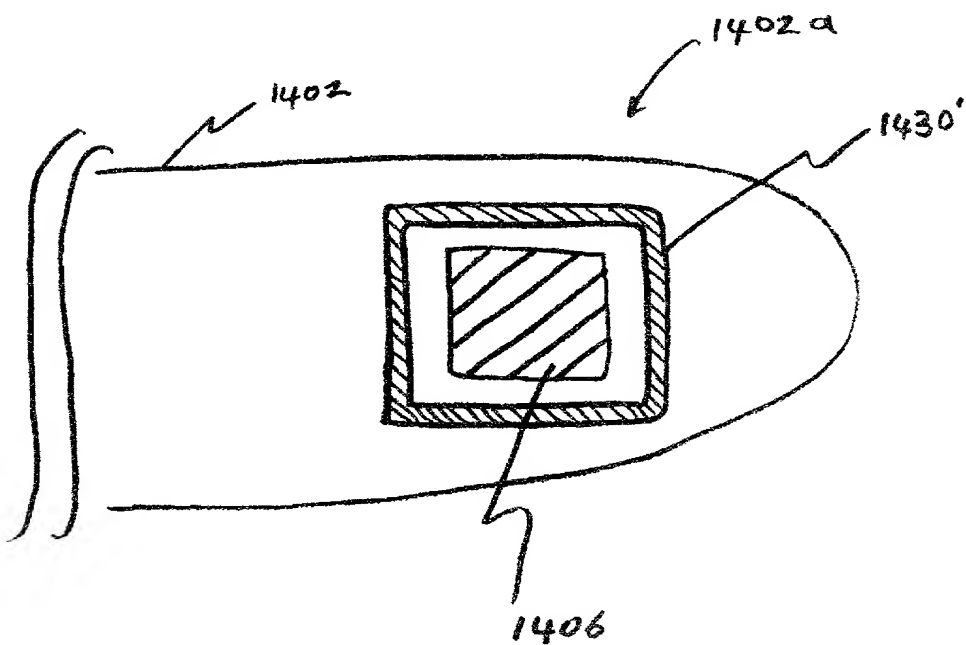


FIG. 44D



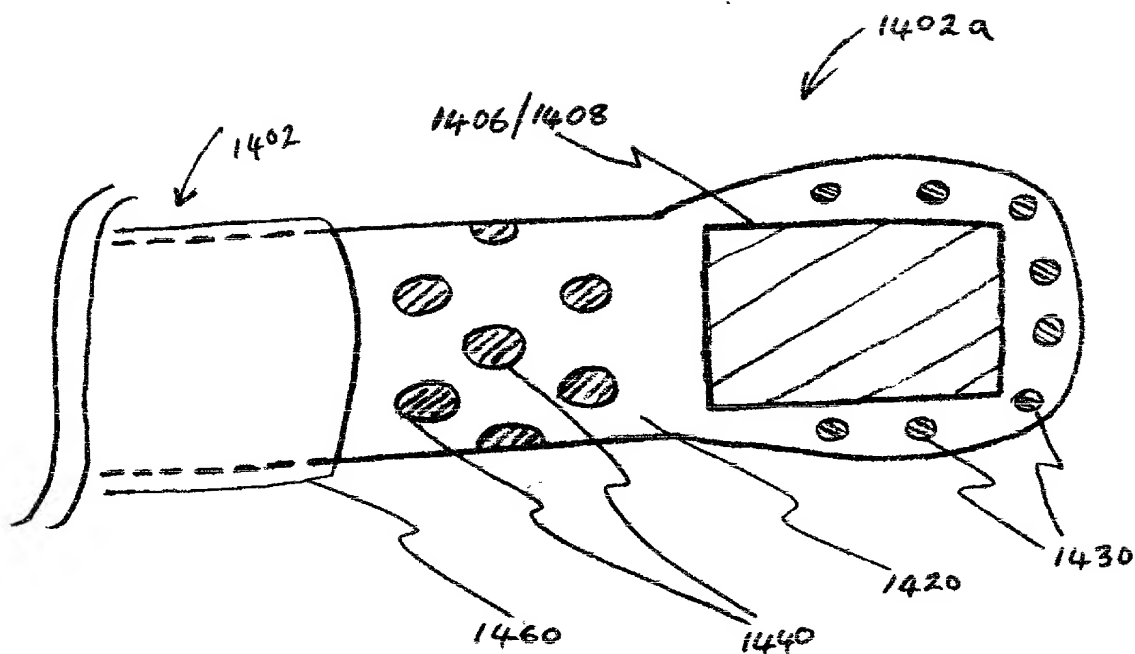


FIG. 45

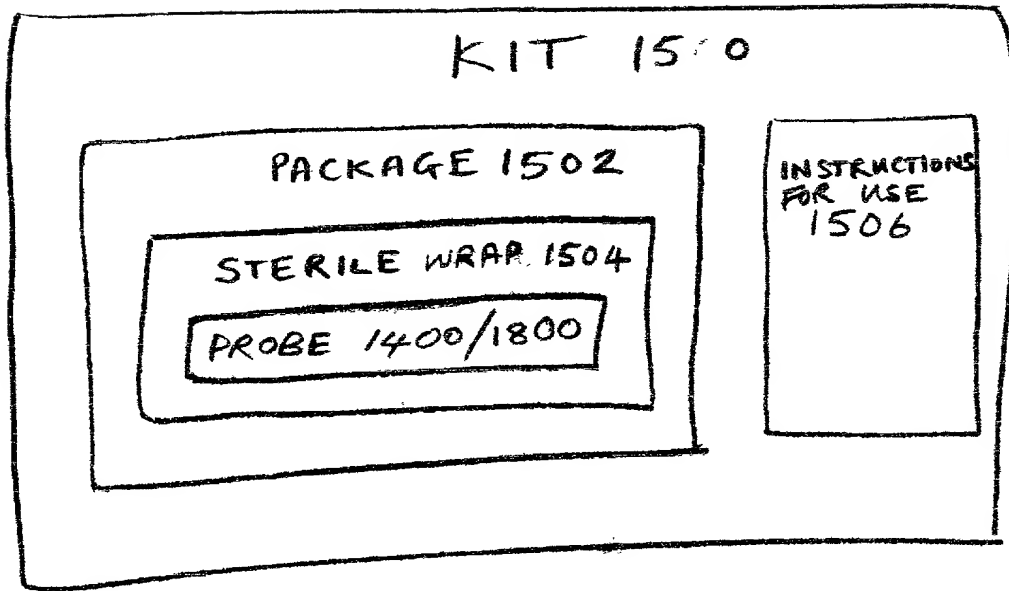


FIG. 46

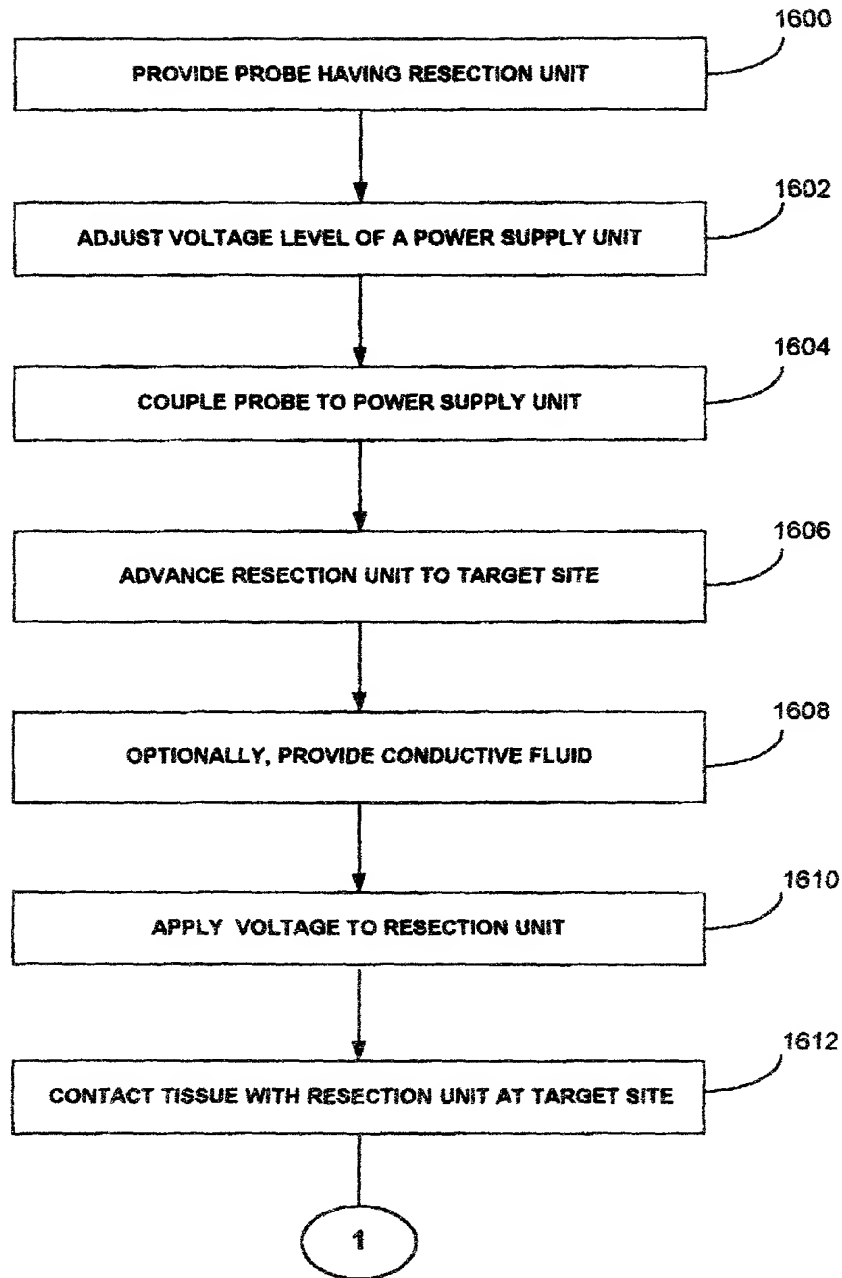


Fig. 47A

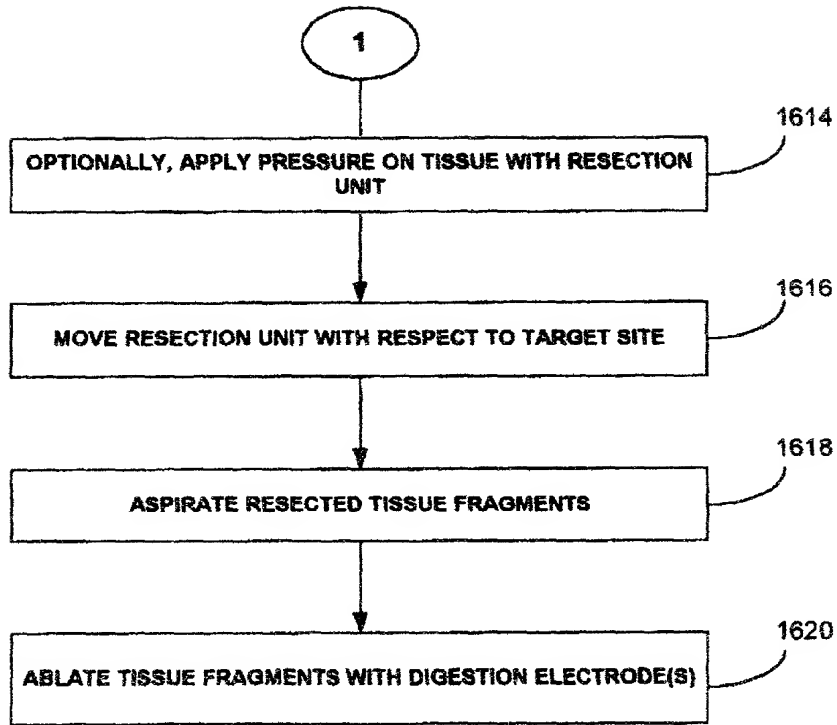
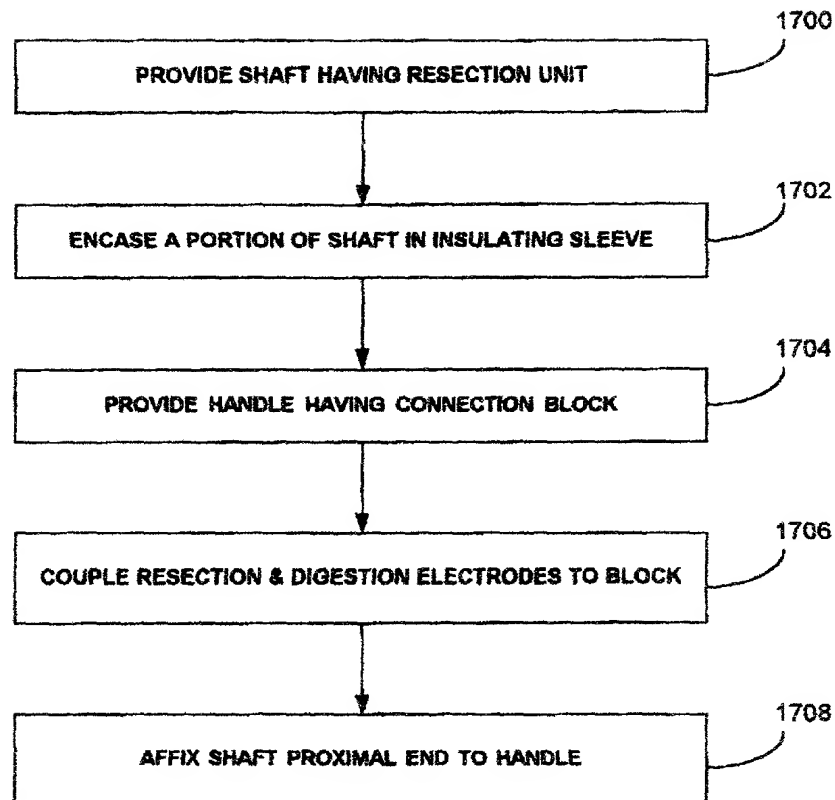


Fig. 47B

**Fig. 48**

## DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **SYSTEMS AND METHODS FOR TISSUE ABLATION AND RESECTION** the specification of which   X   is attached hereto or    was filed on    as Application No.            and was amended on    (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56. I claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

## Prior Foreign Application(s)

Country	Application No.	Date of Filing	Priority Claimed Under 35 USC 119
			Yes <u>  </u> No <u>  </u>

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date
60/210,567	June 9, 2000

I claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application No.	Date of Filing	Status
09/197,013	November 20, 1998	<u>  </u> Patented <u>  X  </u> Pending <u>  </u> Abandoned
09/010,382	January 21, 1998	<u>  </u> Patented <u>  X  </u> Pending <u>  </u> Abandoned
08/990,374	December 15, 1997	<u>  </u> Patented <u>  X  </u> Pending <u>  </u> Abandoned
08/485,219	June 7, 1995	<u>  X  </u> Patented <u>  </u> Pending <u>  </u> Abandoned



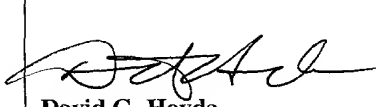
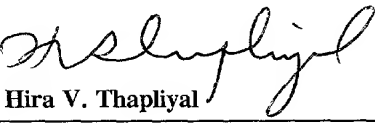
**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

**John T. Raffle, Reg. No. 38,585**

Send Correspondence to:  <b>ArthroCare Corporation</b> <b>595 N. Pastoria Avenue</b> <b>Sunnyvale, California 94085-2936</b>	Direct Telephone Calls to: (Name, Reg. No., Telephone No.)  <b>Name: John T. Raffle</b> <b>Reg. No.: 38,585</b> <b>Telephone: (408) 736-0224</b>
--	---

Full Name of Inventor 1	Last Name <b>WOLOSZKO</b>	First Name <b>JEAN</b>	Middle Name or Initial	
Residence & Citizenship	City <b>Mountain View</b>	State/Foreign Country <b>California</b>	Country of Citizenship <b>France</b>	
Post Office Address	Post Office Address <b>1694 Columbia Drive</b>	City <b>Mountain View</b>	State/Country <b>California</b>	Zip Code <b>94040</b>
Full Name of Inventor 2	Last Name <b>DAVISON</b>	First Name <b>TERRY</b>	Middle Name or Initial <b>S.</b>	
Residence & Citizenship	City <b>Cupertino</b>	State/Foreign Country <b>California</b>	Country of Citizenship <b>Canada</b>	
Post Office Address	Post Office Address <b>10398 #B Meadow Place</b>	City <b>Cupertino</b>	State/Country <b>California</b>	Zip Code <b>95014</b>
Full Name of Inventor 3	Last Name <b>HOVDA</b>	First Name <b>DAVID</b>	Middle Name or Initial <b>C.</b>	
Residence & Citizenship	City <b>Mountain View</b>	State/Foreign Country <b>California</b>	Country of Citizenship <b>United States of America</b>	
Post Office Address	Post Office Address <b>1900 Miramonte Avenue</b>	City <b>Mountain View</b>	State/Country <b>California</b>	Zip Code <b>94040</b>
Full Name of Inventor 4	Last Name <b>THAPLIYAL</b>	First Name <b>HIRA</b>	Middle Name or Initial <b>V.</b>	
Residence & Citizenship	City <b>Los Altos</b>	State/Foreign Country <b>California</b>	Country of Citizenship <b>United States of America</b>	
Post Office Address	Post Office Address <b>1192 Volti Lane</b>	City <b>Los Altos</b>	State/Country <b>California</b>	Zip Code <b>94024</b>
Full Name of Inventor 5	Last Name <b>EGGERS</b>	First Name <b>PHILIP</b>	Middle Name or Initial <b>E.</b>	
Residence & Citizenship	City <b>Dublin</b>	State/Foreign Country <b>Ohio</b>	Country of Citizenship <b>United States of America</b>	
Post Office Address	Post Office Address <b>5366 Reserve Drive</b>	City <b>Dublin</b>	State/Country <b>Ohio</b>	Zip Code <b>43017</b>

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1  <b>Jean Woloszko</b>	Signature of Inventor 2  <b>Terry S. Davison</b>	Signature of Inventor 3  <b>David C. Hovda</b>
Date <u>10/28/00</u>	Date <u>11/3/00</u>	Date <u>11/6/00</u>
Signature of Inventor 4  <b>Hira V. Thapliyal</b>	Signature of Inventor 5  <b>Philip E. Eggers</b>	
Date <u>10/30/00</u>	Date	Date

003077 SE060260

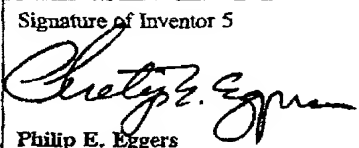


Oct 24 00 02:44p

ArthroCare Corporation

408-530-9143

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
Jean Woloszko	Terry S. Davison	David C. Hovda
Date	Date	Date
Signature of Inventor 4	Signature of Inventor 5	
Hira V. Thapliyal	 Philip E. Eggers	
Date	Date 10/30/00	Date